

US3522227 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:57:05

All time stamps listed in this document are displayed in GMT

US3522227

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

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[Participant ID](#)

US3522227

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

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US3522227

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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

US3522227

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	ATRIAL FIBRILLATION
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)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	COPD
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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	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)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	HYPERLIPIDEMIA
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)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	CARDIOMYOPATHY
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)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	OBSTRUCTIVE SLEEP APNEA
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)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	MIGRAINES
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)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	BENIGN PROSTATIC HYPERPLASIA
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)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	OVERACTIVE BLADDER
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)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Condition	MORBID OBESITY
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)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:36 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:36
Height ( <i>xxx.x</i> )	69 in
Weight ( <i>xxx.x</i> )	259 lb
BMI ( <i>xxx.x</i> )	38.32759 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:40:06

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:40:06

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:40:06

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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 18:31:20

Generated On: 10 Jun 2021 07:57:05

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

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

What was the participant's randomization number? 187044

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:36
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 18:31:20

Generated On: 10 Jun 2021 07:57:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:43
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 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 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:13 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 14:13

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 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

19 AUG 2020 14:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:10	19 AUG 2020 14:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 14:43

PC Open Date & Time

19 AUG 2020 14:33

PC Close Date & Time

19 AUG 2020 17:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 19 AUG 2020 18:42

PC Open Date & Time 19 AUG 2020 17:58

PC Close Date & Time 20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

20 AUG 2020 12:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 17:56

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 00:26

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 AUG 2020 12:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:45

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 13:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 14:43

PC Open Date & Time

19 AUG 2020 14:33

PC Close Date & Time

19 AUG 2020 17:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 18:42

PC Open Date & Time

19 AUG 2020 17:58

PC Close Date & Time

20 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 12:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 17:56

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 00:26

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 14:46

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 13:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 14:44
PC Open Date & Time	19 AUG 2020 14:33
PC Close Date & Time	19 AUG 2020 17:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 18:43
PC Open Date & Time	19 AUG 2020 17:58
PC Close Date & Time	20 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:42
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 17:57
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 00:27
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:03
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2333

EAB) (1725)



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 14:46
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 2333

EAB) (1725)

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 13:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments LEFT A VOICEMAIL

*If Contact Not Made, please provide Comments*

US3522227

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

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 CALL ATTEMPTED WITH NO  
ANSWER, LEFT VOICEMAIL.  
*If Contact Not Made, please provide Comments*

US3522227

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT A MESSAGE

*If Contact Not Made, please provide Comments*



US3522227

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 13:27
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3522227

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 12:57 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 12:57

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

US3522227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	12:50 (24 HR)
Collection date and time (derived)	17 SEP 2020 12:50

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:56	17 SEP 2020 12:56
Nasopharyngeal Swab 2	No		



US3522227

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

17 SEP 2020 13:28

PC Open Date & Time

17 SEP 2020 13:17

PC Close Date & Time

17 SEP 2020 15:47

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	17 SEP 2020 17:11
PC Open Date & Time	17 SEP 2020 16:42
PC Close Date & Time	18 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 16:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 15:37

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

21 SEP 2020 13:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

22 SEP 2020 12:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:02

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 13:18

PC Open Date & Time

17 SEP 2020 13:17

PC Close Date & Time

17 SEP 2020 15:47

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 17:11

PC Open Date & Time

17 SEP 2020 16:42

PC Close Date & Time

18 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 16:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 15:38

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 13:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 13:18
PC Open Date & Time	17 SEP 2020 13:17
PC Close Date & Time	17 SEP 2020 15:47

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 17:12
PC Open Date & Time	17 SEP 2020 16:42
PC Close Date & Time	18 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 16:15
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 15:38
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

107 of 2333

EAB) (1725)

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:32
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

109 of 2333

EAB) (1725)

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:03
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:03
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

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

US3522227

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

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

US3522227

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3522227

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:44
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522227

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3522227

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	12:50 (24 HR)
Collection date and time (derived)	15 OCT 2020 12:50

US3522227

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:31:20

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 01:19:33
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 07:28:46

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 03:39:25

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 00:02:54

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 14:38:03
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 06:18:10

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:04:07

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 03:14:52

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 17:59:39

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 12:00:41

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 00:07:04

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 23:31:49

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 08:01:16

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 12:53:29

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 00:02:07

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 10:52:55

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 07:43:58
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 07:06:11

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 14:55:55

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 10:00:08

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 07:42:22

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 09:17:53

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 07:39:09

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 07:44:08

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 13:48:30

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 16:46:41

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 07:39:54

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 20:05:11

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 278

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 299

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 376

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 397

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 418

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 432

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 439

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 467

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 474

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2021 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 488

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

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

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**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 502

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 530

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 APR 2022 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 628

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

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

**US3522227**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 726

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59
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US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

US3522227

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 07:57:05**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:04:11

US3522227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

Please select one status for the follow-up contact Contact Made ☒  
Contact Not Made ☐

Comments "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*

US3522227

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 DEC 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments  
*If Contact Not Made, please provide Comments*  
NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE

US3522227

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

"NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK."



US3522227

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 15:19:45

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

Please select one status for the follow-up contact Contact Made ☒  
Contact Not Made ☐

Comments NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK.

*If Contact Not Made, please provide Comments*

US3522227

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:35:40

Generated On: 10 Jun 2021 07:57:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 12:09
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522227

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3522227

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 MAR 2021

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

5 MAR 2021 12:20

US3522227

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522227

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 19:01:58

Generated On: 10 Jun 2021 07:57:05

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

*If Contact Not Made, please provide Comments*

NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE

US3522227

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 19:01:58

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact Contact Made ☐  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3522227**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522227

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:05

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3522227

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:57:05

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:09:07

Generated On: 10 Jun 2021 07:57:05

Date of updated informed consent ( <i>dd MMM yyyy</i> )	8 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> )	8 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



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 12:10
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	13:01 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 13:01
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)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 JAN 2021

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 12:30

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

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

12:10 (24 HR)

Collection date and time (derived)

8 JAN 2021 12:10

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	12:15
Collection Date and Time (derived)	8 JAN 2021 12:15

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522227

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

Please select one status for the follow-up contact Contact Made ☒  
Contact Not Made ☐

Comments "NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK."

*If Contact Not Made, please provide Comments*

US3522227

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:06

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3522227

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 12:17
Temperature (xxx.x)	98.6 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 12:50
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	TEMPORAL
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3522227

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3522227

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 FEB 2021

What was the treatment time? (00:00-23:59) 12:20 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 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

US3522227

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522227

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3522227

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522227

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 12:09
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522227

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3522227

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:03:30

Generated On: 10 Jun 2021 07:57:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 MAR 2021
Collection time (00:00-23:59)	12:20 (24 HR)
Collection date and time (derived)	5 MAR 2021 12:20

US3522227

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

AEID	USA-US131-2021-MRNA-1273-P30 1000002
Adverse event	ATRIAL FIBRILLATION EXACERBATION
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)	6 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	6 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	7 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 15:40:04

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

---

PT WAS ADMITTED TO  
OBSERVATION FLOOR AT  
BEAUMONT FOR A HR  
RANGING FROM 40-140.  
(RELATED TO HX OF AFIB) .PT  
HAD SOB AND CHEST  
HEAVINESS. HE WAS  
ADMITTED AND ALL TESTS  
WERE NEGATIVE. THEY TOLD  
HIM TO STOP TAKING  
METFORMIN. SYMPTOMS ARE  
NO LONGER THERE AND  
PATIENT STATES HE FEELS  
FINE. HE IS FOLLOWING UP  
WITH HIS PCP AT VA.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 05 Mar 2021 15:40:05

**Generated On: 10 Jun 2021 07:57:05**

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

---

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication SYNTHROID

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 0.075

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

2 ON SUNDAY, 1 MONDAY  
THROUGH SATURDAY

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication	SYMBICORT
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COPD
Dose per administration	160/4.5
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication Tiotropium Bromide

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☒  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

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 (6)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication PROSCAR

Prophylaxis Yes ☐  
No ☒

Indication BPH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication ZOCOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication FLOMAX

Prophylaxis Yes ☐  
No ☒

Indication BPH

Dose per administration 0.4

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication FIORICET

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication VALIUM

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 15:40:04

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☒  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication DOFETILIDE

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 500

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication DITROPAN

Prophylaxis Yes ☐  
No ☒

Indication OVERACTIVE BLADDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication MORBID OBESITY/WEIGHT LOSS

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 15:40:04

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Name of Medication FLU SHOT

Prophylaxis Yes ☒  
No ☐

Indication ANNUAL VACCINE

Dose per administration UNKNOWN

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

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 (17)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU

Dose per administration UNKNOWN

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

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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US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		8 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

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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US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 15:40:04

Generated On: 10 Jun 2021 07:57:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
6 JAN 2021	ELECTROCARDIOGRAPHY	Adverse Event	
6 JAN 2021	CT HEART	Adverse Event	
6 JAN 2021	NUCLEAR STRESS TEST	Adverse Event	

US3522227

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:57:05

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3522227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:57:05

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

SAEID	USA-US131-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

SAEID	USA-US131-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/JAN/2021 11:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

SAEID	USA-US131-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 20:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

SAEID	USA-US131-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/JAN/2021 15:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 15:40:05

Generated On: 10 Jun 2021 07:57:05

SAEID	USA-US131-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/FEB/2021 14:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522227 (Prod: Henry Ford Health System)

**US3522227**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:57:05**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'US3522227'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:14:45

US3522227

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:04:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:38:53

US3522227

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:04:09
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:14:46

US3522227

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:04:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 17:38:53

**US3522227**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'SCRN'	System	19 Aug 2020 17:38:53



US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:14:47

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '67'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'YEARS'	System	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered '67'	System	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered 'Male (M)'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08



US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:39:08

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 17:39:31



US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'Aug 2020'	System	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered '2020'	System	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:39:31

US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:05:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:14:46



US3522227

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'I'	System	19 Aug 2020 17:40:16

US3522227

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:57:05

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:40:16

US3522227

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:57:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:06:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:48:17

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:27
Data point term sent to Coder	System	19 Aug 2020 18:27:50
User entered 'atrial fibrillation'	(b) (4), (b) (6)	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:27:01



US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:01

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:28
Data point term sent to Coder	System	19 Aug 2020 18:27:51
User entered 'COPD'	(b) (4), (b) (6)	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:27:25



US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:25

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:27
Data point term sent to Coder	System	19 Aug 2020 18:27:51
User entered 'Depression'	(b) (4), (b) (6)	19 Aug 2020 18:27:47



US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:47



US3522227

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:27:47

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:28
Data point term sent to Coder	System	19 Aug 2020 18:28:52
User entered 'GERD'	(b) (4), (b) (6)	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:11



US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:11

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:29:28
Data point term sent to Coder	System	19 Aug 2020 18:28:53
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:28:47



US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:28:47

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:31:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:31:21
Data point term sent to Coder	System	19 Aug 2020 18:29:54
User entered 'Hypertension'	(b) (4), (b) (6)	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:29:02



US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:02

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:31:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:31:22
Data point term sent to Coder	System	19 Aug 2020 18:29:55
User entered 'Cardiomyopathy'	(b) (4), (b) (6)	19 Aug 2020 18:29:24



US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:24



US3522227

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:29:24

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:31:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:31:22
Data point term sent to Coder	System	19 Aug 2020 18:30:58
User entered 'Hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:30:50



US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:30:50

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:33:27
Data point term sent to Coder	System	19 Aug 2020 18:31:59
User entered 'Obstructive sleep apnea'	(b) (4), (b) (6)	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:31:29



US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:31:29

(

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:29

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:33:27
Data point term sent to Coder	System	19 Aug 2020 18:32:02
User entered 'Migraines'	(b) (4), (b) (6)	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:31:55



US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:31:55

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:12:48
Data point term sent to Coder	System	30 Sep 2020 18:11:43
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	30 Sep 2020 18:10:43
User entered 'Benign Prostatic Hyperplasia' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Sep 2020 18:10:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:34:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:34:28
Data point term sent to Coder	System	19 Aug 2020 18:33:02
User entered 'BPH'	(b) (4), (b) (6)	19 Aug 2020 18:32:14



US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:14



US3522227

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:14

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable cardioverter defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:12:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:12:46
Data point term sent to Coder	System	19 Aug 2020 18:33:05
User entered 'implantable cardioverter-defibrillator'	(b) (4), (b) (6)	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:33:43
Query 'Per DM CLR: Please review the status of this Sharon Mathys procedure as the effects of the procedure may be Ongoing but the procedure itself is not. Review and update eCRF as appropriate. ' answered with 'ok' (Site from DM).	(b) (4) (b) (4)	30 Sep 2020 18:12:34
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Sep 2020 18:12:21
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:37:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	30 Sep 2020 18:12:21
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:35



US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 18:32:35

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:23
Data point term sent to Coder	System	19 Aug 2020 19:05:28
User entered 'Overactive bladder'	(b) (4), (b) (6)	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:13



US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:05:13

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:20
Data point term sent to Coder	System	19 Aug 2020 19:08:38
User entered 'Morbid obesity'	(b) (4), (b) (6)	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 19:08:02



US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:08:12
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:57:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered empty.	System	19 Aug 2020 19:08:02

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:40:49



US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:16:42
User closed query 'Per source, time of vital sign assessment is 1336. Please confirm and correct.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:16:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Query 'Per source, time of vital sign assessment is 1336. Please confirm and correct.' answered with 'corrected' (Site from CRA).	(b) (4)	
	Sharon Mathys (b) (4)	04 Mar 2021 18:09:19
	(b) (4)	
User entered '13:36' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Mar 2021 18:08:46
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 03:09:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:09:43
	(b) (4), (b) (6)	
User opened query 'Per source, time of vital sign assessment is 1336. Please confirm and correct.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 03:09:33
	(b) (4), (b) (6)	
User entered '13:40'	(b) (4), (b) (6)	19 Aug 2020 17:40:49
	(b) (4), (b) (6)	

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered '19 Aug 2020 13:36'	System	04 Mar 2021 18:08:46
User entered '19 Aug 2020 13:40'	System	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:41:16
User entered '69' in reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:41:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:40:49
User entered '69' (non-conformant).	(b) (4), (b) (6)	19 Aug 2020 17:40:49
DataPoint set to visible.	System	19 Aug 2020 17:40:16

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:41:16
User entered '259' lb reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:41:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:40:49
User entered '259' (non-conformant).	(b) (4), (b) (6)	19 Aug 2020 17:40:49
DataPoint set to visible.	System	19 Aug 2020 17:40:16

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
Amendment Manager: User entered '38.32759'	System	17 Sep 2020 00:14:19
User entered '38.3'	System	19 Aug 2020 17:41:16
User entered empty.	System	19 Aug 2020 17:40:49
DataPoint set to visible.	System	19 Aug 2020 17:40:16

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'kg/m2'	System	19 Aug 2020 17:41:16
User entered empty.	System	19 Aug 2020 17:40:49
DataPoint set to visible.	System	19 Aug 2020 17:40:16

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Aug 2020 17:40:49



US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 15:32:13
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 14:59:41
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'ok' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 14:59:37
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 08:02:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'bpm'	System	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'breaths/min'	System	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'mmHg'	System	19 Aug 2020 17:40:49



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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:09:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Aug 2020 17:40:49

US3522227

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User entered 'mmHg'	System	19 Aug 2020 17:40:49

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:41:29

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:16
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 17:41:29

US3522227

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43



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Folder: Screening

Form: Risk of Exposure

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**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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

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Generated On: 10 Jun 2021 07:57:05

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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[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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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[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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43



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Folder: Screening

Form: Risk of Exposure

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**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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

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**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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 17:42:43



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Folder: Screening

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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)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:42:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:26:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 03:10:42
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:42:43

US3522227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:42:53

US3522227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:42:53

US3522227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:42:53

US3522227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'VISIT1'	System	19 Aug 2020 17:42:53

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:29:19



US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 05:37:00
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:37:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:29:19
User entered '187044' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:29:19

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 17:29:19

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:44:06

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:44:06

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:44:06

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:44:06

US3522227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:11:56
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:44:06

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:20
User entered '69' in	(b) (4), (b) (6)	19 Aug 2020 17:45:56



US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:20
User entered '259' lb	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:20
User entered '69' in	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:20
User entered '259' lb	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '13:36' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 18:19:45
User entered '13:34'	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered '19 Aug 2020 13:36'	System	05 Nov 2020 18:19:45
User entered '19 Aug 2020 13:34'	System	19 Aug 2020 17:45:56



US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '98.4' F	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '55'	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'bpm'	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:16:16
User closed query 'RR Rate is not documented in source. Please confirm and correct.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:16:14
Query 'RR Rate is not documented in source. Please confirm and correct.' answered with 'added' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 14:19:51
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:04
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User opened query 'RR Rate is not documented in source. Please confirm and correct.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 03:13:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '13'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'breaths/min'	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '125'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56



US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'mmHg'	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '78'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'mmHg'	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:20
User entered '69' in	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:20
User entered '259' lb	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 18:49:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 17:45:56
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4)	(b) (4)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:49:52
	(b) (4), (b) (6)	19 Aug 2020 17:45:56



US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:31:20
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:36:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Vitals taken in 30 min' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:53:04
User entered '14:43' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:52:45
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 18:49:52
User entered '14:35' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered '19 Aug 2020 14:43'	System	19 Aug 2020 18:52:45
User entered '19 Aug 2020 14:35'	System	19 Aug 2020 18:49:52
User entered empty.	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'bpm'	System	19 Aug 2020 18:49:52
User entered empty.	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '14' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56



US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'breaths/min'	System	19 Aug 2020 18:49:52
User entered empty.	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '122' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'mmHg'	System	19 Aug 2020 18:49:52
User entered empty.	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:49:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:56:07
User entered 'mmHg'	System	19 Aug 2020 18:49:52
User entered empty.	System	19 Aug 2020 17:45:56

US3522227

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:15
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Aug 2020 17:47:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:46:35

US3522227

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:15
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 17:47:05
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 17:46:35

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:03



US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '14:13'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '19 Aug 2020 14:13'	System	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:29
User entered 'ONCE'	System	19 Aug 2020 18:40:03



US3522227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 18:40:03

US3522227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:38

US3522227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:38

US3522227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:14:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '14:05' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Aug 2020 18:41:13
User entered '14:10'	(b) (4), (b) (6)	19 Aug 2020 18:40:38

US3522227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '19 Aug 2020 14:05'	System	19 Aug 2020 18:41:13
User entered '19 Aug 2020 14:10'	System	19 Aug 2020 18:40:38

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:15:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:15:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:41:47



US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:15:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '14:10'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '19 Aug 2020 14:10'	System	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:15:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	19 Aug 2020 18:42:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 18:42:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:42:21
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:41:47
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:15:08
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered empty.	System	19 Aug 2020 18:41:47

US3522227

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:15:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:47:02

US3522227

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '1'	System	19 Aug 2020 18:47:02



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:42:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5d028201-301d-4774-b2db-8d314810da16' User entered 'Yes (Y)'	System	19 Aug 2020 18:43:13
	System	19 Aug 2020 18:43:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:03', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5d028201-301d-4774-b2db-8d314810da16' User entered '98.1'	System	19 Aug 2020 18:43:13
	System	19 Aug 2020 18:43:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5d028201-301d-4774-b2db-8d314810da16'	System	19 Aug 2020 18:43:13
User entered 'No (N)'	System	19 Aug 2020 18:43:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5d028201-301d-4774-b2db-8d314810da16' User entered '19 Aug 2020 14:43'	System	19 Aug 2020 18:43:13
	System	19 Aug 2020 18:43:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 14:33'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 17:03'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7319de80-fca0-4b65-8996-fbafb7dc1da5' User entered 'Yes (Y)'	System	19 Aug 2020 22:42:29
	System	19 Aug 2020 22:42:29

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7319de80-fca0-4b65-8996-fbafb7dc1da5' User entered '98.1'	System	19 Aug 2020 22:42:29
	System	19 Aug 2020 22:42:29

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:19', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7319de80-fca0-4b65-8996-fbafb7dc1da5'	System	19 Aug 2020 22:42:29
User entered 'No (N)'	System	19 Aug 2020 22:42:29

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:28', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7319de80-fca0-4b65-8996-fbafb7dc1da5'	System	19 Aug 2020 22:42:29
User entered '19 Aug 2020 18:42'	System	19 Aug 2020 22:42:29

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 17:58'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 2'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:21', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '18cf0142-a169-4a3d-84e8-ee5f1c2223da' User entered 'Yes (Y)'	System	20 Aug 2020 16:41:41
	System	20 Aug 2020 16:41:41



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:27', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '18cf0142-a169-4a3d-84e8-ee5f1c2223da' User entered '98.1'	System	20 Aug 2020 16:41:41
	System	20 Aug 2020 16:41:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:33', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '18cf0142-a169-4a3d-84e8-ee5f1c2223da'	System	20 Aug 2020 16:41:41
User entered 'No (N)'	System	20 Aug 2020 16:41:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:37', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '18cf0142-a169-4a3d-84e8-ee5f1c2223da' User entered '20 Aug 2020 12:41'	System	20 Aug 2020 16:41:41
	System	20 Aug 2020 16:41:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 3'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '032fd1c7-3506-46dc-9dca-ab06189c65bf' User entered 'Yes (Y)'	System	21 Aug 2020 21:56:41
	System	21 Aug 2020 21:56:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:31', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '032fd1c7-3506-46dc-9dca-ab06189c65bf' User entered '96.6'	System	21 Aug 2020 21:56:41
	System	21 Aug 2020 21:56:41



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:35', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '032fd1c7-3506-46dc-9dca-ab06189c65bf' User entered 'No (N)'	System	21 Aug 2020 21:56:41
	System	21 Aug 2020 21:56:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:38', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '032fd1c7-3506-46dc-9dca-ab06189c65bf' User entered '21 Aug 2020 17:56'	System	21 Aug 2020 21:56:41
	System	21 Aug 2020 21:56:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 4'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:19', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7f2b7b38-dc4b-4891-8741-21db88afb6e9'	System	23 Aug 2020 04:26:36
User entered 'Yes (Y)'	System	23 Aug 2020 04:26:36

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:25', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7f2b7b38-dc4b-4891-8741-21db88afb6e9' User entered '98.7'	System	23 Aug 2020 04:26:36
	System	23 Aug 2020 04:26:36

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:31', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7f2b7b38-dc4b-4891-8741-21db88afb6e9'	System	23 Aug 2020 04:26:36
User entered 'No (N)'	System	23 Aug 2020 04:26:36



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:35', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7f2b7b38-dc4b-4891-8741-21db88afb6e9'	System	23 Aug 2020 04:26:36
User entered '23 Aug 2020 00:26'	System	23 Aug 2020 04:26:36

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 5'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:02:48', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'daf790de-0a9c-4318-ae81-40a411e7e8f8'	System	23 Aug 2020 16:03:04
User entered 'Yes (Y)'	System	23 Aug 2020 16:03:04

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:02:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'daf790de-0a9c-4318-ae81-40a411e7e8f8' User entered '98.2'	System	23 Aug 2020 16:03:04
	System	23 Aug 2020 16:03:04

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:02:58', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'daf790de-0a9c-4318-ae81-40a411e7e8f8'	System	23 Aug 2020 16:03:04
User entered 'No (N)'	System	23 Aug 2020 16:03:04

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'daf790de-0a9c-4318-ae81-40a411e7e8f8'	System	23 Aug 2020 16:03:04
User entered '23 Aug 2020 12:03'	System	23 Aug 2020 16:03:04



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 6'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:24', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7a4bab9a-4d0e-4f07-abcb-3bbb45ab4fdb' User entered 'Yes (Y)'	System	24 Aug 2020 18:45:41
	System	24 Aug 2020 18:45:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:30', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7a4bab9a-4d0e-4f07-abcb-3bbb45ab4fdb' User entered '98.6'	System	24 Aug 2020 18:45:41
	System	24 Aug 2020 18:45:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:33', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7a4bab9a-4d0e-4f07-abc-b3bbb45ab4fdb' User entered 'No (N)'	System	24 Aug 2020 18:45:41
	System	24 Aug 2020 18:45:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:39', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '7a4bab9a-4d0e-4f07-abc4-3bbb45ab4fdb' User entered '24 Aug 2020 14:45'	System	24 Aug 2020 18:45:41
	System	24 Aug 2020 18:45:41

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 7'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:05:28', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '227feb78-f57f-4176-b9ed-6aed87ee0163'	System	25 Aug 2020 17:06:13
User entered 'Yes (Y)'	System	25 Aug 2020 17:06:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:05:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '227feb78-f57f-4176-b9ed-6aed87ee0163' User entered '97.6'	System	25 Aug 2020 17:06:13
	System	25 Aug 2020 17:06:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:08', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '227feb78-f57f-4176-b9ed-6aed87ee0163'	System	25 Aug 2020 17:06:13
User entered 'No (N)'	System	25 Aug 2020 17:06:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '227feb78-f57f-4176-b9ed-6aed87ee0163'	System	25 Aug 2020 17:06:13
User entered '25 Aug 2020 13:06'	System	25 Aug 2020 17:06:13

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:19', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '23643fd8-e37d-4408-a41f-af7ff83696b1' User entered 'None (1)'	System	19 Aug 2020 18:43:53
	System	19 Aug 2020 18:43:53

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:35', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '23643fd8-e37d-4408-a41f-af7ff83696b1' User entered 'No (N)'	System	19 Aug 2020 18:43:53
	System	19 Aug 2020 18:43:53

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:40', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '23643fd8-e37d-4408-a41f-af7ff83696b1' User entered 'No (N)'	System	19 Aug 2020 18:43:53
	System	19 Aug 2020 18:43:53

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '23643fd8-e37d-4408-a41f-af7ff83696b1' User entered 'None (1)'	System	19 Aug 2020 18:43:53
	System	19 Aug 2020 18:43:53

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:50', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '23643fd8-e37d-4408-a41f-af7ff83696b1' User entered '19 Aug 2020 14:43'	System	19 Aug 2020 18:43:53
	System	19 Aug 2020 18:43:53

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 14:33'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 17:03'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:33', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c97bffce-f162-4c00-9534-47d61fe1d707'	System	19 Aug 2020 22:42:52
User entered 'None (1)'	System	19 Aug 2020 22:42:52

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:36', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c97bffce-f162-4c00-9534-47d61fe1d707'	System	19 Aug 2020 22:42:52
User entered 'No (N)'	System	19 Aug 2020 22:42:52

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:43', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c97bffce-f162-4c00-9534-47d61fe1d707'	System	19 Aug 2020 22:42:52
User entered 'No (N)'	System	19 Aug 2020 22:42:52

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c97bffce-f162-4c00-9534-47d61fe1d707'	System	19 Aug 2020 22:42:52
User entered 'None (1)'	System	19 Aug 2020 22:42:52

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:50', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c97bffce-f162-4c00-9534-47d61fe1d707'	System	19 Aug 2020 22:42:52
User entered '19 Aug 2020 18:42'	System	19 Aug 2020 22:42:52

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 17:58'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 2'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:42', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc3ad7b4-a622-41ad-83e2-85bce0ddd47d' User entered 'None (1)'	System	20 Aug 2020 16:41:58
	System	20 Aug 2020 16:41:58

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:46', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc3ad7b4-a622-41ad-83e2-85bce0ddd47d' User entered 'No (N)'	System	20 Aug 2020 16:41:58
	System	20 Aug 2020 16:41:58

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc3ad7b4-a622-41ad-83e2-85bce0ddd47d' User entered 'No (N)'	System	20 Aug 2020 16:41:58
	System	20 Aug 2020 16:41:58

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:51', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc3ad7b4-a622-41ad-83e2-85bce0ddd47d' User entered 'None (1)'	System	20 Aug 2020 16:41:58
	System	20 Aug 2020 16:41:58

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc3ad7b4-a622-41ad-83e2-85bce0ddd47d' User entered '20 Aug 2020 12:41'	System	20 Aug 2020 16:41:58
	System	20 Aug 2020 16:41:58

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 3'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:42', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc16fbe1-ec67-4231-a4bd-a7c2c87ec1c3'	System	21 Aug 2020 21:57:01
User entered 'None (1)'	System	21 Aug 2020 21:57:01

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:45', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc16fbe1-ec67-4231-a4bd-a7c2c87ec1c3'	System	21 Aug 2020 21:57:01
User entered 'No (N)'	System	21 Aug 2020 21:57:01

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:48', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc16fbe1-ec67-4231-a4bd-a7c2c87ec1c3'	System	21 Aug 2020 21:57:01
User entered 'No (N)'	System	21 Aug 2020 21:57:01

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:53', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc16fbe1-ec67-4231-a4bd-a7c2c87ec1c3' User entered 'None (1)'	System	21 Aug 2020 21:57:01
	System	21 Aug 2020 21:57:01

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:56:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc16fbe1-ec67-4231-a4bd-a7c2c87ec1c3' User entered '21 Aug 2020 17:56'	System	21 Aug 2020 21:57:01
	System	21 Aug 2020 21:57:01

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 4'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0164d837-a9a7-4f13-a416-1081ec910667'	System	23 Aug 2020 04:27:00
User entered 'None (1)'	System	23 Aug 2020 04:27:00

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:45', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0164d837-a9a7-4f13-a416-1081ec910667' User entered 'No (N)'	System	23 Aug 2020 04:27:00
	System	23 Aug 2020 04:27:00

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:48', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0164d837-a9a7-4f13-a416-1081ec910667' User entered 'No (N)'	System	23 Aug 2020 04:27:00
	System	23 Aug 2020 04:27:00

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0164d837-a9a7-4f13-a416-1081ec910667' User entered 'None (1)'	System	23 Aug 2020 04:27:00
	System	23 Aug 2020 04:27:00

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:26:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0164d837-a9a7-4f13-a416-1081ec910667' User entered '23 Aug 2020 00:26'	System	23 Aug 2020 04:27:00
	System	23 Aug 2020 04:27:00

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 5'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'cc2c14ac-5774-401f-a398-aecb9d0edb5b' User entered 'None (1)'	System	23 Aug 2020 16:03:18
	System	23 Aug 2020 16:03:18

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:08', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'cc2c14ac-5774-401f-a398-aecb9d0edb5b' User entered 'No (N)'	System	23 Aug 2020 16:03:18
	System	23 Aug 2020 16:03:18

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:10', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'cc2c14ac-5774-401f-a398-aecb9d0edb5b' User entered 'No (N)'	System	23 Aug 2020 16:03:18
	System	23 Aug 2020 16:03:18

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:13', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'cc2c14ac-5774-401f-a398-aecb9d0edb5b' User entered 'None (1)'	System	23 Aug 2020 16:03:18
	System	23 Aug 2020 16:03:18

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'cc2c14ac-5774-401f-a398-aecb9d0edb5b' User entered '23 Aug 2020 12:03'	System	23 Aug 2020 16:03:18
	System	23 Aug 2020 16:03:18

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 6'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:43', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '90cd07dc-5e69-4089-a63b-48f9e57d1e0a' User entered 'None (1)'	System	24 Aug 2020 18:46:07
	System	24 Aug 2020 18:46:07

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '90cd07dc-5e69-4089-a63b-48f9e57d1e0a' User entered 'No (N)'	System	24 Aug 2020 18:46:07
	System	24 Aug 2020 18:46:07

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:45:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '90cd07dc-5e69-4089-a63b-48f9e57d1e0a' User entered 'No (N)'	System	24 Aug 2020 18:46:07
	System	24 Aug 2020 18:46:07

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '90cd07dc-5e69-4089-a63b-48f9e57d1e0a' User entered 'None (1)'	System	24 Aug 2020 18:46:07
	System	24 Aug 2020 18:46:07

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '90cd07dc-5e69-4089-a63b-48f9e57d1e0a' User entered '24 Aug 2020 14:46'	System	24 Aug 2020 18:46:07
	System	24 Aug 2020 18:46:07

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 7'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:17', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fce30d0f-694c-45f8-a561-1ad9659d82f0'	System	25 Aug 2020 17:06:39
User entered 'None (1)'	System	25 Aug 2020 17:06:39

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:20', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fce30d0f-694c-45f8-a561-1ad9659d82f0'	System	25 Aug 2020 17:06:39
User entered 'No (N)'	System	25 Aug 2020 17:06:39

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:25', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fce30d0f-694c-45f8-a561-1ad9659d82f0'	System	25 Aug 2020 17:06:39
User entered 'No (N)'	System	25 Aug 2020 17:06:39

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:32', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fce30d0f-694c-45f8-a561-1ad9659d82f0'	System	25 Aug 2020 17:06:39
User entered 'None (1)'	System	25 Aug 2020 17:06:39

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:36', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fce30d0f-694c-45f8-a561-1ad9659d82f0' User entered '25 Aug 2020 13:06'	System	25 Aug 2020 17:06:39
	System	25 Aug 2020 17:06:39

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:43:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'None (0)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:02', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'None (0)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:10', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'None (0)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:13', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'None (0)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'None (0)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:17', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'None (0)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:22', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered 'No (N)'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T14:44:25', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd32c87d6-9823-44c0-8e09-1ab5321953ef' User entered '19 Aug 2020 14:44'	System	19 Aug 2020 18:44:27
	System	19 Aug 2020 18:44:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 14:33'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 17:03'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'None (0)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:42:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'None (0)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:43:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'None (0)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:43:02', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'None (0)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:43:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'None (0)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:43:06', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'None (0)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:43:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered 'No (N)'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-19T18:43:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'da3cac61-3243-4d8e-a5f5-db3af1f09c43' User entered '19 Aug 2020 18:43'	System	19 Aug 2020 22:43:19
	System	19 Aug 2020 22:43:19

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Aug 2020 17:58'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 2'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:41:58', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'None (0)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'None (0)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:03', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'None (0)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:06', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'None (0)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:08', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'None (0)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'None (0)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:14', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered 'No (N)'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-20T12:42:17', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f3c01834-a6aa-4cb7-8f6b-15106596ff4a' User entered '20 Aug 2020 12:42'	System	20 Aug 2020 16:42:21
	System	20 Aug 2020 16:42:21

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 3'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'None (0)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'None (0)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:08', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'None (0)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'None (0)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:14', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'None (0)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:16', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'None (0)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:20', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered 'No (N)'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-21T17:57:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3f17161-83fa-4178-bdcc-7619845be24d' User entered '21 Aug 2020 17:57'	System	21 Aug 2020 21:57:27
	System	21 Aug 2020 21:57:27

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 4'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2' User entered 'None (0)'	System	23 Aug 2020 04:27:23
	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2' User entered 'None (0)'	System	23 Aug 2020 04:27:23
	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:06', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2' User entered 'None (0)'	System	23 Aug 2020 04:27:23
	System	23 Aug 2020 04:27:23



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2' User entered 'None (0)'	System	23 Aug 2020 04:27:23
	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2' User entered 'None (0)'	System	23 Aug 2020 04:27:23
	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:14', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2'	System	23 Aug 2020 04:27:23
User entered 'None (0)'	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:17', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2'	System	23 Aug 2020 04:27:23
User entered 'No (N)'	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T00:27:20', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '03b0c2ea-b59b-4c40-a9b4-67afc29fa5f2' User entered '23 Aug 2020 00:27'	System	23 Aug 2020 04:27:23
	System	23 Aug 2020 04:27:23

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 5'	System	19 Aug 2020 18:40:03



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:19', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'None (0)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:22', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'None (0)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:24', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'None (0)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'None (0)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:28', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'None (0)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:30', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'None (0)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:34', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered 'No (N)'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-23T12:03:36', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '41f6a1d2-35b3-45a8-984a-797d230effa5' User entered '23 Aug 2020 12:03'	System	23 Aug 2020 16:03:40
	System	23 Aug 2020 16:03:40



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 6'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abebd' User entered 'None (0)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abebd' User entered 'None (0)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abebd' User entered 'None (0)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:18', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abe bd' User entered 'None (0)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:21', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abebd' User entered 'None (0)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abe bd' User entered 'None (0)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abebd' User entered 'No (N)'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-24T14:46:29', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fdefa43c-1ec7-445b-9657-a6fa221abe bd' User entered '24 Aug 2020 14:46'	System	24 Aug 2020 18:46:34
	System	24 Aug 2020 18:46:34

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 7'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:40', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'None (0)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:42', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'None (0)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04



US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:45', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'None (0)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'None (0)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'None (0)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:51', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'None (0)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:06:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered 'No (N)'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-08-25T13:07:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f4ab43b0-1566-4dbc-89a5-339713a632da' User entered '25 Aug 2020 13:07'	System	25 Aug 2020 17:07:04
	System	25 Aug 2020 17:07:04

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:40:03

US3522227

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:40:03



US3522227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:19:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4)	
	Yaman Ahmed (b) (4)	26 Aug 2020 22:59:09
	(b) (4)	

US3522227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:19:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '26 Aug 2020'	(b) (4)	
	Yaman Ahmed (b) (4)	26 Aug 2020 22:59:09
	(b) (4)	

US3522227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:19:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	26 Aug 2020 22:59:09

US3522227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:19:23
User closed query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 06:01:03
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
Query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' answered with '1 attempt on 1 day' (Site from CRA).	(b) (4)	
	Sharon Mathys (b) (4)	02 Oct 2020 14:37:35
	(b) (4)	
User opened query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 15:39:13
User entered 'Left a voicemail'	Yaman Ahmed (b) (4)	26 Aug 2020 22:59:09
	(b) (4)	

US3522227

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:19:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	02 Sep 2020 15:10:24

US3522227

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	02 Sep 2020 15:10:24

US3522227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:27:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4) (b) (4)	02 Sep 2020 15:13:04

US3522227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:27:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '2 Sep 2020'	(b) (4) Alandra White (b) (4) (b) (4)	02 Sep 2020 15:13:04



US3522227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:27:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Alandra White (b) (4) (b) (4)	02 Sep 2020 15:13:04

US3522227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:27:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4)	
Query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' answered with '1 attempt on 1 day' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:58:19
Query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' answered with '1 attempt on 1 day' (Site from CRA).	Sharon Mathys (b) (4)	02 Oct 2020 14:37:07
User opened query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 15:39:22
User entered 'Call attempted with no answer, left voicemail.'	Alandra White (b) (4)	02 Sep 2020 15:13:04

US3522227

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:27:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:20:06

US3522227

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	09 Sep 2020 18:20:06

US3522227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:04:40

US3522227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '09 Sep 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:04:40

US3522227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Sharon Mathys (b) (4)	04 Mar 2021 19:04:40

US3522227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Left a message'	(b) (4) Sharon Mathys (b) (4) (b) (4)	04 Mar 2021 19:04:40



US3522227

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:24:53
User closed query 'Please complete Safety Call Day 22 page. Per source, only one contact attempt was made a message left.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:24:50
Query 'Please complete Safety Call Day 22 page. Per Sharon Mathys source, only one contact attempt was made a message left.' answered with 'updated' (Site from CRA).	(b) (4)	04 Mar 2021 19:22:55
User opened query 'Please complete Safety Call Day 22 page. Per source, only one contact attempt was made a message left.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 03:35:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 16:50:15

US3522227

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:32
User entered 'I'	System	17 Sep 2020 16:50:15

US3522227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:36:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 16:51:19

US3522227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:36:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:51:19

US3522227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:36:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:51:19

US3522227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'VISIT2'	System	17 Sep 2020 16:51:19

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:52:12



US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12:40'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '17 Sep 2020 12:40'	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '98.2' F	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'temporal'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '61'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'bpm'	System	17 Sep 2020 16:52:12



US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '16'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'breaths/min'	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '137'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '88'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 17:10:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:10:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:10:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 16:52:12
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12



US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:32:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:32:56
User entered '13:27' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:56
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '17 Sep 2020 13:27'	System	17 Sep 2020 17:32:56
User entered empty.	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:32:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:32:56
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:56
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:10:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:32:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:32:56
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:56
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'bpm'	System	17 Sep 2020 17:32:56
User entered empty.	System	17 Sep 2020 16:52:12



US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:32:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:32:56
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:56
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'breaths/min'	System	17 Sep 2020 17:32:56
User entered empty.	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:32:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:32:56
User entered '123' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:56
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	17 Sep 2020 17:32:56
User entered empty.	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:40:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:32:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:32:56
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:32:56
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:10:55
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	17 Sep 2020 17:32:56
User entered empty.	System	17 Sep 2020 16:52:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:52:19

US3522227

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 16:52:19



US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12:57'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '17 Sep 2020 12:57'	System	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:09



US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:41:35
User entered 'ONCE'	System	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 17:09:09

US3522227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:46:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:55

US3522227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:46:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:55

US3522227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:46:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12:50'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:09:55

US3522227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '17 Sep 2020 12:50'	System	17 Sep 2020 17:09:55

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:47:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 17:10:12



US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12:56'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '17 Sep 2020 12:56'	System	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered empty.	System	17 Sep 2020 17:10:12

US3522227

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 03:47:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:10:18



US3522227

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	17 Sep 2020 17:10:18

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:28:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c4896c69-9536-4ab1-be3f-cf54699a1e78' User entered 'Yes (Y)'	System	17 Sep 2020 17:28:55
	System	17 Sep 2020 17:28:55

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:28:46', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c4896c69-9536-4ab1-be3f-cf54699a1e78' User entered '97.4'	System	17 Sep 2020 17:28:55
	System	17 Sep 2020 17:28:55

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:28:50', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c4896c69-9536-4ab1-be3f-cf54699a1e78' User entered 'No (N)'	System	17 Sep 2020 17:28:55
	System	17 Sep 2020 17:28:55

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:28:53', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c4896c69-9536-4ab1-be3f-cf54699a1e78' User entered '17 Sep 2020 13:28'	System	17 Sep 2020 17:28:55
	System	17 Sep 2020 17:28:55

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 13:17'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 15:47'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:10:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'badf5387-0048-4e49-ad8c-ffa6666b1db7' User entered 'Yes (Y)'	System	17 Sep 2020 21:11:12
	System	17 Sep 2020 21:11:12

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'badf5387-0048-4e49-ad8c-ffa6666b1db7' User entered '98.4'	System	17 Sep 2020 21:11:12
	System	17 Sep 2020 21:11:12

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'badf5387-0048-4e49-ad8c-ffa6666b1db7'	System	17 Sep 2020 21:11:12
User entered 'No (N)'	System	17 Sep 2020 21:11:12

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'badf5387-0048-4e49-ad8c-ffa6666b1db7' User entered '17 Sep 2020 17:11'	System	17 Sep 2020 21:11:12
	System	17 Sep 2020 21:11:12

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 16:42'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 2'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:24', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e41d8673-f162-4e77-a8f9-604efacc0978' User entered 'Yes (Y)'	System	18 Sep 2020 20:14:41
	System	18 Sep 2020 20:14:41

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:31', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e41d8673-f162-4e77-a8f9-604efacc0978' User entered '98.0'	System	18 Sep 2020 20:14:41
	System	18 Sep 2020 20:14:41

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:35', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e41d8673-f162-4e77-a8f9-604efacc0978'	System	18 Sep 2020 20:14:41
User entered 'No (N)'	System	18 Sep 2020 20:14:41

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:39', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e41d8673-f162-4e77-a8f9-604efacc0978'	System	18 Sep 2020 20:14:41
User entered '18 Sep 2020 16:14'	System	18 Sep 2020 20:14:41

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 3'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:31', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'a2b946cd-a748-4550-afa5-b59c68fdc3a8' User entered 'Yes (Y)'	System	19 Sep 2020 19:37:47
	System	19 Sep 2020 19:37:47



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:37', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'a2b946cd-a748-4550-afa5-b59c68fdc3a8' User entered '98.0'	System	19 Sep 2020 19:37:47
	System	19 Sep 2020 19:37:47

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'a2b946cd-a748-4550-afa5-b59c68fdc3a8' User entered 'No (N)'	System	19 Sep 2020 19:37:47
	System	19 Sep 2020 19:37:47

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:44', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'a2b946cd-a748-4550-afa5-b59c68fdc3a8' User entered '19 Sep 2020 15:37'	System	19 Sep 2020 19:37:47
	System	19 Sep 2020 19:37:47

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 4'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d2a40d5-f7cc-49a2-b7c2-cb93d672462f' User entered 'Yes (Y)'	System	20 Sep 2020 16:01:37
	System	20 Sep 2020 16:01:37

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d2a40d5-f7cc-49a2-b7c2-cb93d672462f' User entered '98.2'	System	20 Sep 2020 16:01:37
	System	20 Sep 2020 16:01:37



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d2a40d5-f7cc-49a2-b7c2-cb93d672462f' User entered 'No (N)'	System	20 Sep 2020 16:01:37
	System	20 Sep 2020 16:01:37

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d2a40d5-f7cc-49a2-b7c2-cb93d672462f' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 16:01:37
	System	20 Sep 2020 16:01:37

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 5'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:34', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc2c0944-2e0c-4ffc-b36a-f96177a6ec7b' User entered 'Yes (Y)'	System	21 Sep 2020 17:31:49
	System	21 Sep 2020 17:31:49

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:38', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc2c0944-2e0c-4ffc-b36a-f96177a6ec7b' User entered '98.2'	System	21 Sep 2020 17:31:49
	System	21 Sep 2020 17:31:49

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc2c0944-2e0c-4ffc-b36a-f96177a6ec7b'	System	21 Sep 2020 17:31:49
User entered 'No (N)'	System	21 Sep 2020 17:31:49



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:43', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'fc2c0944-2e0c-4ffc-b36a-f96177a6ec7b' User entered '21 Sep 2020 13:31'	System	21 Sep 2020 17:31:49
	System	21 Sep 2020 17:31:49

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 6'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:17', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '20aeb8d8-9ecf-4aa8-a4ac-d0ca80c2cf9e' User entered 'Yes (Y)'	System	22 Sep 2020 16:03:43
	System	22 Sep 2020 16:03:43

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:21', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '20aeb8d8-9ecf-4aa8-a4ac-d0ca80c2cf9e' User entered '98.4'	System	22 Sep 2020 16:03:43
	System	22 Sep 2020 16:03:43

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '20aeb8d8-9ecf-4aa8-a4ac-d0ca80c2cf9e'	System	22 Sep 2020 16:03:43
User entered 'No (N)'	System	22 Sep 2020 16:03:43

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '20aeb8d8-9ecf-4aa8-a4ac-d0ca80c2cf9e' User entered '22 Sep 2020 12:02'	System	22 Sep 2020 16:03:43
	System	22 Sep 2020 16:03:43



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 7'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:02:43', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '64c8c65a-22de-4f1b-95ea-d670bc1d2bbc' User entered 'Yes (Y)'	System	23 Sep 2020 16:04:13
	System	23 Sep 2020 16:04:13

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:02:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '64c8c65a-22de-4f1b-95ea-d670bc1d2bbc' User entered '96.7'	System	23 Sep 2020 16:04:13
	System	23 Sep 2020 16:04:13

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:02:51', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '64c8c65a-22de-4f1b-95ea-d670bc1d2bbc' User entered 'No (N)'	System	23 Sep 2020 16:04:13
	System	23 Sep 2020 16:04:13

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:02:53', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '64c8c65a-22de-4f1b-95ea-d670bc1d2bbc' User entered '23 Sep 2020 12:02'	System	23 Sep 2020 16:04:13
	System	23 Sep 2020 16:04:13

US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:17:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '62f07e02-16d1-4691-ada5-6382f847069b' User entered 'None (1)'	System	17 Sep 2020 17:18:06
	System	17 Sep 2020 17:18:06

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:17:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '62f07e02-16d1-4691-ada5-6382f847069b' User entered 'No (N)'	System	17 Sep 2020 17:18:06
	System	17 Sep 2020 17:18:06

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:17:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '62f07e02-16d1-4691-ada5-6382f847069b' User entered 'No (N)'	System	17 Sep 2020 17:18:06
	System	17 Sep 2020 17:18:06

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:17:58', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '62f07e02-16d1-4691-ada5-6382f847069b' User entered 'None (1)'	System	17 Sep 2020 17:18:06
	System	17 Sep 2020 17:18:06

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:02', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '62f07e02-16d1-4691-ada5-6382f847069b' User entered '17 Sep 2020 13:18'	System	17 Sep 2020 17:18:06
	System	17 Sep 2020 17:18:06

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 13:17'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 15:47'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:13', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '98748163-1cd0-461c-b1bc-2f6559db4057'	System	17 Sep 2020 21:11:28
User entered 'None (1)'	System	17 Sep 2020 21:11:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:16', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '98748163-1cd0-461c-b1bc-2f6559db4057' User entered 'No (N)'	System	17 Sep 2020 21:11:28
	System	17 Sep 2020 21:11:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:19', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '98748163-1cd0-461c-b1bc-2f6559db4057' User entered 'No (N)'	System	17 Sep 2020 21:11:28
	System	17 Sep 2020 21:11:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '98748163-1cd0-461c-b1bc-2f6559db4057'	System	17 Sep 2020 21:11:28
User entered 'None (1)'	System	17 Sep 2020 21:11:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '98748163-1cd0-461c-b1bc-2f6559db4057' User entered '17 Sep 2020 17:11'	System	17 Sep 2020 21:11:28
	System	17 Sep 2020 21:11:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 16:42'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 2'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:43', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3b177d84-4313-401c-a512-4f3b029f5dcb' User entered 'None (1)'	System	18 Sep 2020 20:15:01
	System	18 Sep 2020 20:15:01

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3b177d84-4313-401c-a512-4f3b029f5dcb' User entered 'No (N)'	System	18 Sep 2020 20:15:01
	System	18 Sep 2020 20:15:01

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:51', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3b177d84-4313-401c-a512-4f3b029f5dcb' User entered 'No (N)'	System	18 Sep 2020 20:15:01
	System	18 Sep 2020 20:15:01

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:53', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3b177d84-4313-401c-a512-4f3b029f5dcb' User entered 'None (1)'	System	18 Sep 2020 20:15:01
	System	18 Sep 2020 20:15:01

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:56', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3b177d84-4313-401c-a512-4f3b029f5dcb' User entered '18 Sep 2020 16:14'	System	18 Sep 2020 20:15:01
	System	18 Sep 2020 20:15:01

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 3'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:48', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'de0972eb-6120-407d-ac8c-b7b9489ab0dc' User entered 'None (1)'	System	19 Sep 2020 19:38:05
	System	19 Sep 2020 19:38:05

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'de0972eb-6120-407d-ac8c-b7b9489ab0dc' User entered 'No (N)'	System	19 Sep 2020 19:38:05
	System	19 Sep 2020 19:38:05

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'de0972eb-6120-407d-ac8c-b7b9489ab0dc' User entered 'No (N)'	System	19 Sep 2020 19:38:05
	System	19 Sep 2020 19:38:05

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:37:59', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'de0972eb-6120-407d-ac8c-b7b9489ab0dc' User entered 'None (1)'	System	19 Sep 2020 19:38:05
	System	19 Sep 2020 19:38:05

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'de0972eb-6120-407d-ac8c-b7b9489ab0dc' User entered '19 Sep 2020 15:38'	System	19 Sep 2020 19:38:05
	System	19 Sep 2020 19:38:05

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 4'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68a92678-5e18-4c41-abd1-ba2484864370' User entered 'None (1)'	System	20 Sep 2020 16:01:58
	System	20 Sep 2020 16:01:58

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:18', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68a92678-5e18-4c41-abd1-ba2484864370' User entered 'No (N)'	System	20 Sep 2020 16:01:58
	System	20 Sep 2020 16:01:58

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:21', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68a92678-5e18-4c41-abd1-ba2484864370' User entered 'No (N)'	System	20 Sep 2020 16:01:58
	System	20 Sep 2020 16:01:58

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68a92678-5e18-4c41-abd1-ba2484864370' User entered 'None (1)'	System	20 Sep 2020 16:01:58
	System	20 Sep 2020 16:01:58

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:25', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68a92678-5e18-4c41-abd1-ba2484864370' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 16:01:58
	System	20 Sep 2020 16:01:58

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 5'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:48', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'ef6984d5-bf86-4b68-9983-593511170bb0'	System	21 Sep 2020 17:32:00
User entered 'None (1)'	System	21 Sep 2020 17:32:00

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:50', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'ef6984d5-bf86-4b68-9983-593511170bb0' User entered 'No (N)'	System	21 Sep 2020 17:32:00
	System	21 Sep 2020 17:32:00

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'ef6984d5-bf86-4b68-9983-593511170bb0' User entered 'No (N)'	System	21 Sep 2020 17:32:00
	System	21 Sep 2020 17:32:00

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'ef6984d5-bf86-4b68-9983-593511170bb0' User entered 'None (1)'	System	21 Sep 2020 17:32:00
	System	21 Sep 2020 17:32:00

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:31:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'ef6984d5-bf86-4b68-9983-593511170bb0' User entered '21 Sep 2020 13:31'	System	21 Sep 2020 17:32:00
	System	21 Sep 2020 17:32:00

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 6'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:30', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3ae5f53-f014-4456-a4a6-66604fffc035'	System	22 Sep 2020 16:04:12
User entered 'None (1)'	System	22 Sep 2020 16:04:12

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:40', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3ae5f53-f014-4456-a4a6-66604fffc035'	System	22 Sep 2020 16:04:12
User entered 'No (N)'	System	22 Sep 2020 16:04:12

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:46', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3ae5f53-f014-4456-a4a6-66604fffc035'	System	22 Sep 2020 16:04:12
User entered 'No (N)'	System	22 Sep 2020 16:04:12

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3ae5f53-f014-4456-a4a6-66604fffc035'	System	22 Sep 2020 16:04:12
User entered 'None (1)'	System	22 Sep 2020 16:04:12

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c3ae5f53-f014-4456-a4a6-66604fffc035'	System	22 Sep 2020 16:04:12
User entered '22 Sep 2020 12:02'	System	22 Sep 2020 16:04:12

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 7'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:02:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5fab5ed5-5682-40d4-b8e2-99a394c70796' User entered 'None (1)'	System	23 Sep 2020 16:04:28
	System	23 Sep 2020 16:04:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5fab5ed5-5682-40d4-b8e2-99a394c70796' User entered 'No (N)'	System	23 Sep 2020 16:04:28
	System	23 Sep 2020 16:04:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:02', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5fab5ed5-5682-40d4-b8e2-99a394c70796' User entered 'No (N)'	System	23 Sep 2020 16:04:28
	System	23 Sep 2020 16:04:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

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 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5fab5ed5-5682-40d4-b8e2-99a394c70796' User entered 'None (1)'	System	23 Sep 2020 16:04:28
	System	23 Sep 2020 16:04:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5fab5ed5-5682-40d4-b8e2-99a394c70796' User entered '23 Sep 2020 12:03'	System	23 Sep 2020 16:04:28
	System	23 Sep 2020 16:04:28

US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:06', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'None (0)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'None (0)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'None (0)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:14', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'None (0)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:17', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'None (0)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:19', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'None (0)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:22', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered 'No (N)'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T13:18:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '2fbe0eae-46ea-4ac3-b02a-48d8568718f0' User entered '17 Sep 2020 13:18'	System	17 Sep 2020 17:18:31
	System	17 Sep 2020 17:18:31

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 13:17'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 15:47'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:38', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950'	System	17 Sep 2020 21:12:06
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered 'None (0)'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:44', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered 'None (0)'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered 'None (0)'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:50', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered 'None (0)'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered 'None (0)'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:11:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered 'No (N)'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-17T17:12:02', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd023ef31-e1d7-45b5-81a9-e54c87481950' User entered '17 Sep 2020 17:12'	System	17 Sep 2020 21:12:06
	System	17 Sep 2020 21:12:06

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '17 Sep 2020 16:42'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 2'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:14:59', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'None (0)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'None (0)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:03', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'None (0)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'None (0)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'None (0)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'None (0)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:12', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered 'No (N)'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-18T16:15:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8ff36b1c-ee43-40a3-8d69-a27f157b36f0' User entered '18 Sep 2020 16:15'	System	18 Sep 2020 20:15:18
	System	18 Sep 2020 20:15:18



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 3'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'None (0)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'None (0)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:09', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'None (0)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'None (0)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:13', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'None (0)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:16', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'None (0)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:18', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered 'No (N)'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-19T15:38:21', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '3d0a2cab-3ec3-4129-9745-54f6fef18cd5' User entered '19 Sep 2020 15:38'	System	19 Sep 2020 19:38:26
	System	19 Sep 2020 19:38:26

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 4'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:29', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'None (0)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:33', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'None (0)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:35', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'None (0)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:37', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'None (0)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:39', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'None (0)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'None (0)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:43', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered 'No (N)'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-20T12:01:46', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8dc64b46-3c64-4e20-a0a9-758898d22cdf' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 16:02:23
	System	20 Sep 2020 16:02:23

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 5'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'None (0)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:06', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'None (0)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:16', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'None (0)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:18', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'None (0)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:20', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'None (0)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'None (0)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered 'No (N)'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-21T13:32:29', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '33eada7a-405f-44fa-97a1-460bd1dd2024' User entered '21 Sep 2020 13:32'	System	21 Sep 2020 17:32:36
	System	21 Sep 2020 17:32:36

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 6'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:56', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'None (0)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:57', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'None (0)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:02:59', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'None (0)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:03:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'None (0)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:03:03', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'None (0)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:03:05', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'None (0)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:03:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered 'No (N)'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-22T12:03:10', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '04a3354f-8ee3-4866-b241-c0eefe59f3a8' User entered '22 Sep 2020 12:03'	System	22 Sep 2020 16:04:21
	System	22 Sep 2020 16:04:21

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	17 Sep 2020 17:09:09
User entered 'Day 7'	System	17 Sep 2020 17:09:09

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'None (0)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:13', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'None (0)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'None (0)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:18', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'None (0)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:20', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'None (0)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:22', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'None (0)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:25', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered 'No (N)'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-09-23T12:03:28', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b0e3e739-4c34-4017-8559-9342489f70a7' User entered '23 Sep 2020 12:03'	System	23 Sep 2020 16:04:43
	System	23 Sep 2020 16:04:43

US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:09:09



US3522227

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:09:09

US3522227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:13:59

US3522227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:13:59

US3522227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:13:59

US3522227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
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)	24 Sep 2020 15:13:59

US3522227

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:17:59

US3522227

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	24 Sep 2020 15:17:59

US3522227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 13:28:35



US3522227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 13:28:35

US3522227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 13:28:35

US3522227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
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)	01 Oct 2020 13:28:35

US3522227

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 13:28:40

US3522227

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	01 Oct 2020 13:28:40

US3522227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:53:18

US3522227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:53:18

US3522227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:53:18



US3522227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:53:18

US3522227

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:53:22

US3522227

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	08 Oct 2020 13:53:22

US3522227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:55:42

US3522227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:55:42

US3522227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:55:42

US3522227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'VISIT3'	System	15 Oct 2020 16:55:42

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41



US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12:44'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '15 Oct 2020 12:44'	System	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '55'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'bpm'	System	15 Oct 2020 16:56:41



US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'breaths/min'	System	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '173'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '74'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	15 Oct 2020 16:56:41

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39

US3522227

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39



US3522227

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:51

US3522227

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:56:51

US3522227

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:57:03

US3522227

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:57:03

US3522227

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered '12:50'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:57:03

US3522227

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '15 Oct 2020 12:50'	System	15 Oct 2020 16:57:03

US3522227

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:31:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:57:17

US3522227

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	15 Oct 2020 16:57:17



US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 64'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-10-19T01:19:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68b831f5-a193-4431-879e-2c99755d4319' User entered 'No (N)'	System	19 Oct 2020 05:19:36
	System	19 Oct 2020 05:19:36

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-10-19T01:19:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68b831f5-a193-4431-879e-2c99755d4319'	System	19 Oct 2020 05:19:36
User entered 'No (N)'	System	19 Oct 2020 05:19:36

**US3522227**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-10-19T01:19:33', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '68b831f5-a193-4431-879e-2c99755d4319' User entered '19 Oct 2020 01:19:33'	System	19 Oct 2020 05:19:36
	System	19 Oct 2020 05:19:36

US3522227

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 71'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-10-26T07:28:36', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '69c7334f-ba3d-4a3b-8ce2-ad57c5fd8d96'	System	26 Oct 2020 11:28:50
User entered 'No (N)'	System	26 Oct 2020 11:28:50



US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-10-26T07:28:42', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '69c7334f-ba3d-4a3b-8ce2-ad57c5fd8d96'	System	26 Oct 2020 11:28:50
User entered 'No (N)'	System	26 Oct 2020 11:28:50

**US3522227**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-10-26T07:28:46', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '69c7334f-ba3d-4a3b-8ce2-ad57c5fd8d96' User entered '26 Oct 2020 07:28:46'	System	26 Oct 2020 11:28:50
	System	26 Oct 2020 11:28:50

US3522227

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 78'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-02T03:39:15', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '67fdb7e4-a5b5-4560-baa8-5b3a4af3a0e8' User entered 'No (N)'	System	02 Nov 2020 08:39:28
	System	02 Nov 2020 08:39:28

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-02T03:39:21', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '67fdb7e4-a5b5-4560-baa8-5b3a4af3a0e8' User entered 'No (N)'	System	02 Nov 2020 08:39:28
	System	02 Nov 2020 08:39:28

**US3522227**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-02T03:39:25', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '67fdb7e4-a5b5-4560-baa8-5b3a4af3a0e8' User entered '02 Nov 2020 03:39:25'	System	02 Nov 2020 08:39:28
	System	02 Nov 2020 08:39:28



US3522227

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 18:40:03

US3522227

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered 'Day 92'	System	19 Aug 2020 18:40:03

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-16T00:02:38', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '9d0e5b28-f864-41d9-ac73-316ef12f0b2a' User entered 'No (N)'	System	16 Nov 2020 05:02:56
	System	16 Nov 2020 05:02:56

US3522227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-16T00:02:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '9d0e5b28-f864-41d9-ac73-316ef12f0b2a'	System	16 Nov 2020 05:02:56
User entered 'No (N)'	System	16 Nov 2020 05:02:56

**US3522227**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-16T00:02:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '9d0e5b28-f864-41d9-ac73-316ef12f0b2a' User entered '16 Nov 2020 00:02:54'	System	16 Nov 2020 05:02:56
	System	16 Nov 2020 05:02:56

US3522227

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 18:40:03

US3522227

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:07:14
Data entry locked.	System	19 Aug 2020 18:40:03
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 18:40:03



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-23T14:37:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'dd9548bb-391f-4bc8-8017-8bffb68fdbb'	System	23 Nov 2020 19:38:09
User entered 'No (N)'	System	23 Nov 2020 19:38:09

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-23T14:37:58', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'dd9548bb-391f-4bc8-8017-8bffb68fdbb'	System	23 Nov 2020 19:38:09
User entered 'No (N)'	System	23 Nov 2020 19:38:09

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-23T14:38:03', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'dd9548bb-391f-4bc8-8017-8bffb68fdbb'	System	23 Nov 2020 19:38:09
User entered '23 Nov 2020 14:38:03'	System	23 Nov 2020 19:38:09

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-27T06:17:58', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '087d365a-b243-4b13-a463-244b879fdc55'	System	27 Nov 2020 11:18:12
User entered 'No (N)'	System	27 Nov 2020 11:18:12



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-27T06:18:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '087d365a-b243-4b13-a463-244b879fdc55'	System	27 Nov 2020 11:18:12
User entered 'No (N)'	System	27 Nov 2020 11:18:12

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-11-27T06:18:10', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '087d365a-b243-4b13-a463-244b879fdc55'	System	27 Nov 2020 11:18:12
User entered '27 Nov 2020 06:18:10'	System	27 Nov 2020 11:18:12

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-04T00:03:54', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c373bae5-5304-45ff-847d-474360b0eacc' User entered 'No (N)'	System	04 Dec 2020 05:04:11

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-04T00:04:01', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c373bae5-5304-45ff-847d-474360b0eacc'	System	04 Dec 2020 05:04:11
User entered 'No (N)'	System	04 Dec 2020 05:04:11

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-04T00:04:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c373bae5-5304-45ff-847d-474360b0eacc' User entered '04 Dec 2020 00:04:07'	System	04 Dec 2020 05:04:11
	System	04 Dec 2020 05:04:11



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-11T03:14:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bedf8c3c-edc4-4f73-af8d-182cb512b1d8'	System	11 Dec 2020 08:14:55
User entered 'No (N)'	System	11 Dec 2020 08:14:55

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-11T03:14:47', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bedf8c3c-edc4-4f73-af8d-182cb512b1d8'	System	11 Dec 2020 08:14:55
User entered 'No (N)'	System	11 Dec 2020 08:14:55

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-11T03:14:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bedf8c3c-edc4-4f73-af8d-182cb512b1d8' User entered '11 Dec 2020 03:14:52'	System	11 Dec 2020 08:14:55
	System	11 Dec 2020 08:14:55

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-21T17:59:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '21e3fc84-d512-46ff-bee6-c21a1bac32db' User entered 'No (N)'	System	21 Dec 2020 22:59:42
	System	21 Dec 2020 22:59:42

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-21T17:59:35', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '21e3fc84-d512-46ff-bee6-c21a1bac32db' User entered 'No (N)'	System	21 Dec 2020 22:59:42
	System	21 Dec 2020 22:59:42

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-21T17:59:39', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '21e3fc84-d512-46ff-bee6-c21a1bac32db' User entered '21 Dec 2020 17:59:39'	System	21 Dec 2020 22:59:42
	System	21 Dec 2020 22:59:42

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-27T12:00:30', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '59c81a46-0d16-446f-a82b-4a2f3edc34e9' User entered 'No (N)'	System	27 Dec 2020 17:00:46
	System	27 Dec 2020 17:00:46



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-27T12:00:38', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '59c81a46-0d16-446f-a82b-4a2f3edc34e9' User entered 'No (N)'	System	27 Dec 2020 17:00:46

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2020-12-27T12:00:41', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '59c81a46-0d16-446f-a82b-4a2f3edc34e9' User entered '27 Dec 2020 12:00:41'	System	27 Dec 2020 17:00:46
	System	27 Dec 2020 17:00:46

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-01T00:06:50', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '79ce1c5c-20e1-48d4-a698-a0f4910c17ba' User entered 'No (N)'	System	01 Jan 2021 05:07:08
	System	01 Jan 2021 05:07:08

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-01T00:07:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '79ce1c5c-20e1-48d4-a698-a0f4910c17ba' User entered 'No (N)'	System	01 Jan 2021 05:07:08
	System	01 Jan 2021 05:07:08

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-01T00:07:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '79ce1c5c-20e1-48d4-a698-a0f4910c17ba' User entered '01 Jan 2021 00:07:04'	System	01 Jan 2021 05:07:08
	System	01 Jan 2021 05:07:08



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-09T23:31:38', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e21c1b03-83cc-4d09-b099-c79c732d3b23'	System	10 Jan 2021 04:31:51
User entered 'No (N)'	System	10 Jan 2021 04:31:51

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-09T23:31:45', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e21c1b03-83cc-4d09-b099-c79c732d3b23'	System	10 Jan 2021 04:31:51
User entered 'No (N)'	System	10 Jan 2021 04:31:51

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-09T23:31:49', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e21c1b03-83cc-4d09-b099-c79c732d3b23' User entered '09 Jan 2021 23:31:49'	System	10 Jan 2021 04:31:51
	System	10 Jan 2021 04:31:51

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-15T08:01:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8fcd081-a5e2-44a7-b3ad-3419d728f5c4'	System	15 Jan 2021 13:01:18
User entered 'No (N)'	System	15 Jan 2021 13:01:18

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-15T08:01:13', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8fcd081-a5e2-44a7-b3ad-3419d728f5c4'	System	15 Jan 2021 13:01:18
User entered 'No (N)'	System	15 Jan 2021 13:01:18

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6F491D18-6715-4FF2-830F-B18E0EEA7382)', Time: '2021-01-15T08:01:16', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '8fcd8081-a5e2-44a7-b3ad-3419d728f5c4' User entered '15 Jan 2021 08:01:16'	System	15 Jan 2021 13:01:18
	System	15 Jan 2021 13:01:18

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-01-22T12:53:23', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '9b9e0ce3-7385-4baf-8441-dac68a1aa2bf' User entered 'No (N)'	System	22 Jan 2021 17:53:33



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-01-22T12:53:26', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '9b9e0ce3-7385-4baf-8441-dac68a1aa2bf'	System	22 Jan 2021 17:53:33
User entered 'No (N)'	System	22 Jan 2021 17:53:33

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-01-22T12:53:29', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '9b9e0ce3-7385-4baf-8441-dac68a1aa2bf' User entered '22 Jan 2021 12:53:29'	System	22 Jan 2021 17:53:33

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-01-29T00:01:51', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0a4498ec-0d66-42d1-9dce-f21a739ac6f0' User entered 'No (N)'	System	29 Jan 2021 05:02:29
	System	29 Jan 2021 05:02:29

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-01-29T00:02:04', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0a4498ec-0d66-42d1-9dce-f21a739ac6f0'	System	29 Jan 2021 05:02:29
User entered 'No (N)'	System	29 Jan 2021 05:02:29

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-01-29T00:02:07', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '0a4498ec-0d66-42d1-9dce-f21a739ac6f0' User entered '29 Jan 2021 00:02:07'	System	29 Jan 2021 05:02:29
	System	29 Jan 2021 05:02:29



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-05T10:52:40', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '01dc5ec9-ff0c-4ab9-bf5a-e4c334a73a1e' User entered 'No (N)'	System	05 Feb 2021 15:52:58
	System	05 Feb 2021 15:52:58

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-05T10:52:51', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '01dc5ec9-ff0c-4ab9-bf5a-e4c334a73a1e' User entered 'No (N)'	System	05 Feb 2021 15:52:58

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-05T10:52:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '01dc5ec9-ff0c-4ab9-bf5a-e4c334a73a1e' User entered '05 Feb 2021 10:52:55'	System	05 Feb 2021 15:52:58
	System	05 Feb 2021 15:52:58

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-12T07:43:52', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '783659aa-62d3-4871-8371-cec27c7ada2f' User entered 'No (N)'	System	12 Feb 2021 12:44:00
	System	12 Feb 2021 12:44:00

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-12T07:43:55', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '783659aa-62d3-4871-8371-cec27c7ada2f' User entered 'No (N)'	System	12 Feb 2021 12:44:00
	System	12 Feb 2021 12:44:00

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-12T07:43:58', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '783659aa-62d3-4871-8371-cec27c7ada2f' User entered '12 Feb 2021 07:43:58'	System	12 Feb 2021 12:44:00
	System	12 Feb 2021 12:44:00

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-19T07:06:02', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5dd0ec95-f0bd-4448-9622-5a737fb2693d' User entered 'No (N)'	System	19 Feb 2021 12:06:14
	System	19 Feb 2021 12:06:14



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-19T07:06:08', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5dd0ec95-f0bd-4448-9622-5a737fb2693d' User entered 'No (N)'	System	19 Feb 2021 12:06:14
	System	19 Feb 2021 12:06:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-19T07:06:11', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5dd0ec95-f0bd-4448-9622-5a737fb2693d' User entered '19 Feb 2021 07:06:11'	System	19 Feb 2021 12:06:14
	System	19 Feb 2021 12:06:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-26T09:55:49-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b42ecf1b-3da6-4ee6-855c-caf50823b691'	System	26 Feb 2021 14:55:57
User entered 'No (N)'	System	26 Feb 2021 14:55:57

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-26T09:55:52-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b42ecf1b-3da6-4ee6-855c-caf50823b691'	System	26 Feb 2021 14:55:57
User entered 'No (N)'	System	26 Feb 2021 14:55:57

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-26T09:55:55-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'b42ecf1b-3da6-4ee6-855c-caf50823b691'	System	26 Feb 2021 14:55:57
User entered '26 Feb 2021 14:55:55'	System	26 Feb 2021 14:55:57



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-09T09:59:59-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f414d3cb-99f1-4c3c-a1d5-e7091b40d7b6'	System	09 Mar 2021 15:00:13
User entered 'No (N)'	System	09 Mar 2021 15:00:13

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-09T10:00:05-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f414d3cb-99f1-4c3c-a1d5-e7091b40d7b6'	System	09 Mar 2021 15:00:13
User entered 'No (N)'	System	09 Mar 2021 15:00:13

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-09T10:00:08-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'f414d3cb-99f1-4c3c-a1d5-e7091b40d7b6' User entered '09 Mar 2021 10:00:08'	System	09 Mar 2021 15:00:13
	System	09 Mar 2021 15:00:13

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-12T07:42:14-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c6fb22d4-a4ba-4886-8724-9b6cd702e35f' User entered 'No (N)'	System	12 Mar 2021 12:42:25
	System	12 Mar 2021 12:42:25

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-12T07:42:19-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c6fb22d4-a4ba-4886-8724-9b6cd702e35f'	System	12 Mar 2021 12:42:25
User entered 'No (N)'	System	12 Mar 2021 12:42:25

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-12T07:42:22-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'c6fb22d4-a4ba-4886-8724-9b6cd702e35f' User entered '12 Mar 2021 07:42:22'	System	12 Mar 2021 12:42:25
	System	12 Mar 2021 12:42:25

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-19T09:17:41-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5caf8203-4bf5-4364-b1b9-71ab601c9a82'	System	19 Mar 2021 13:17:55
User entered 'No (N)'	System	19 Mar 2021 13:17:55



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-19T09:17:49-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5caf8203-4bf5-4364-b1b9-71ab601c9a82'	System	19 Mar 2021 13:17:55
User entered 'No (N)'	System	19 Mar 2021 13:17:55

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-19T09:17:53-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '5caf8203-4bf5-4364-b1b9-71ab601c9a82' User entered '19 Mar 2021 09:17:53'	System	19 Mar 2021 13:17:55
	System	19 Mar 2021 13:17:55

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-26T07:39:02-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '879180ef-e812-4551-bf7b-f50afe06af16' User entered 'No (N)'	System	26 Mar 2021 11:39:12
	System	26 Mar 2021 11:39:12

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-26T07:39:06-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '879180ef-e812-4551-bf7b-f50afe06af16'	System	26 Mar 2021 11:39:12
User entered 'No (N)'	System	26 Mar 2021 11:39:12

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-03-26T07:39:09-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '879180ef-e812-4551-bf7b-f50afe06af16'	System	26 Mar 2021 11:39:12
User entered '26 Mar 2021 07:39:09'	System	26 Mar 2021 11:39:12



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-02T07:44:01-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd79b52b1-0a29-456a-9b9e-39023aa06f1e' User entered 'No (N)'	System	02 Apr 2021 11:44:10
	System	02 Apr 2021 11:44:10

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-02T07:44:05-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd79b52b1-0a29-456a-9b9e-39023aa06f1e' User entered 'No (N)'	System	02 Apr 2021 11:44:10
	System	02 Apr 2021 11:44:10

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-02T07:44:08-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'd79b52b1-0a29-456a-9b9e-39023aa06f1e'	System	02 Apr 2021 11:44:10
User entered '02 Apr 2021 07:44:08'	System	02 Apr 2021 11:44:10

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:05:14



US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-11T13:48:23-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '14d5f3b3-dee1-45f8-844d-f5aaa1a53620'	System	11 Apr 2021 17:48:37
User entered 'No (N)'	System	11 Apr 2021 17:48:37

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-11T13:48:27-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '14d5f3b3-dee1-45f8-844d-f5aaa1a53620'	System	11 Apr 2021 17:48:37
User entered 'No (N)'	System	11 Apr 2021 17:48:37

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-11T13:48:30-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '14d5f3b3-dee1-45f8-844d-f5aaa1a53620'	System	11 Apr 2021 17:48:37
User entered '11 Apr 2021 13:48:30'	System	11 Apr 2021 17:48:37

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-16T16:46:28-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '539a98bd-025d-4715-99c9-37439093f9b0'	System	16 Apr 2021 20:46:43
User entered 'No (N)'	System	16 Apr 2021 20:46:43



US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-16T16:46:37-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '539a98bd-025d-4715-99c9-37439093f9b0' User entered 'No (N)'	System	16 Apr 2021 20:46:43
	System	16 Apr 2021 20:46:43

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-16T16:46:41-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '539a98bd-025d-4715-99c9-37439093f9b0' User entered '16 Apr 2021 16:46:41'	System	16 Apr 2021 20:46:43
	System	16 Apr 2021 20:46:43

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-23T07:39:47-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e6c51422-e0d8-4337-93f0-1d52e7b252c3'	System	23 Apr 2021 11:39:56
User entered 'No (N)'	System	23 Apr 2021 11:39:56

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-23T07:39:51-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e6c51422-e0d8-4337-93f0-1d52e7b252c3' User entered 'No (N)'	System	23 Apr 2021 11:39:56
	System	23 Apr 2021 11:39:56

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-04-23T07:39:54-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'e6c51422-e0d8-4337-93f0-1d52e7b252c3'	System	23 Apr 2021 11:39:56
User entered '23 Apr 2021 07:39:54'	System	23 Apr 2021 11:39:56



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-05-01T20:05:05-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc31a760-2c27-48ae-841d-73a2b723abc9' User entered 'No (N)'	System	02 May 2021 00:05:17
	System	02 May 2021 00:05:17

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-05-01T20:05:08-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc31a760-2c27-48ae-841d-73a2b723abc9'	System	02 May 2021 00:05:17
User entered 'No (N)'	System	02 May 2021 00:05:17

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-05-01T20:05:11-04:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: 'bc31a760-2c27-48ae-841d-73a2b723abc9'	System	02 May 2021 00:05:17
User entered '01 May 2021 20:05:11'	System	02 May 2021 00:05:17

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:05:14

US3522227

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:05:14



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:05:14



**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:05:14

US3522227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:05

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:05:14

**US3522227**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:05:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:05:14

US3522227

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:57:05**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-27T11:04:08-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '4e010f6e-3be5-42e4-9b16-60632326a3f8'	System	27 Feb 2021 16:04:13
User entered 'No (N)'	System	27 Feb 2021 16:04:13



US3522227

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:57:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3CBFE583-268E-4BDD-84C3-3B611ABD899D)', Time: '2021-02-27T11:04:11-05:00', User OID: 'PatientReportedOutcome (US3522227)', ODM File OID: '4e010f6e-3be5-42e4-9b16-60632326a3f8'	System	27 Feb 2021 16:04:13
User entered '27 Feb 2021 16:04:11'	System	27 Feb 2021 16:04:13

US3522227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:02

US3522227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:02

US3522227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:02

US3522227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
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)	12 Nov 2020 15:22:02

US3522227

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:05

US3522227

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	12 Nov 2020 15:22:05

US3522227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	16 Dec 2020 19:28:38



US3522227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '16 Dec 2020'	(b) (4) Yaman Ahmed (b) (4)	16 Dec 2020 19:28:38

US3522227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	16 Dec 2020 19:28:38

US3522227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	(b) (4) Yaman Ahmed (b) (4)	16 Dec 2020 19:28:38

US3522227

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	16 Dec 2020 19:28:43

US3522227

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User entered 'I'	System	16 Dec 2020 19:28:43

US3522227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:35

US3522227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:35

US3522227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:35



US3522227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
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)	14 Jan 2021 20:08:35

US3522227

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:39

US3522227

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:36
User entered 'I'	System	14 Jan 2021 20:08:39

US3522227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:19:45
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 16:09:48

US3522227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:19:45
User entered '12 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 16:09:48

US3522227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:19:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 16:09:48

US3522227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:19:45
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 16:09:48

US3522227

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:55



US3522227

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	05 Mar 2021 17:10:55

US3522227

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:11:04

US3522227

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:11:04

US3522227

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:11:04

US3522227

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'VISIT4'	System	05 Mar 2021 17:11:04

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '5 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '12:09'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23



US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '5 Mar 2021 12:09'	System	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '98.4' F	Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered 'Other (Other)'	Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered 'temporal'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '50'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'bpm'	System	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '15'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'breaths/min'	System	30 Mar 2021 18:52:23



US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '135'	Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:35:40
User entered '67'	Yaman Ahmed (b) (4)	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'mmHg'	System	30 Mar 2021 18:52:23

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39

US3522227

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39

US3522227

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:11:10

US3522227

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:11:10



US3522227

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:22:54

US3522227

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:22:54

**US3522227**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:05**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '12:20'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:22:54

US3522227

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered '5 Mar 2021 12:20'	System	05 Mar 2021 17:22:54

US3522227

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:23:01

US3522227

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:34:39
User entered 'I'	System	05 Mar 2021 17:23:01

US3522227

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:04

US3522227

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:58
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:04



US3522227

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:04

US3522227

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:58
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:04

US3522227

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:08

**US3522227**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 16:29:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:01:52

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:01:52

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change:	System	08 Jan 2021 18:01:55
Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 18:01:55
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).		
User entered empty.	System	08 Jan 2021 18:01:52
	(b) (4), (b) (6)	08 Jan 2021 18:01:52

**US3522227**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 18:01:52



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:08

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:05**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:09:07
User entered '0'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 11:47:06
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:47:34

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:09:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 11:47:06
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:47:34

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 07:44:02
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 07:44:02
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 18:02:08



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:08

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:05**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '1'	System	08 Jan 2021 18:02:08

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:05**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'I'	System	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered empty.	System	08 Jan 2021 18:03:53
DataPoint set to visible.	System	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered empty.	System	08 Jan 2021 18:03:53
DataPoint set to visible.	System	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	08 Jan 2021 18:04:25
User entered '12:10' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 18:04:25
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	08 Jan 2021 18:03:53
User entered '12:36'	(b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '8 Jan 2021 12:10'	System	08 Jan 2021 18:04:25
User entered '8 Jan 2021 12:36'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '60'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'bpm'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'breaths/min'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '135'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '74'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53



US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered empty.	System	08 Jan 2021 18:03:53
DataPoint set to visible.	System	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '13:01'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53



US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '8 Jan 2021 13:01'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '53'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'bpm'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'breaths/min'	System	08 Jan 2021 18:03:53



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '121'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '74'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:03:53

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	08 Jan 2021 18:03:53

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:04:01

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:04:01

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:50



US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:05**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mRNA-1273'	System	08 Jan 2021 18:02:50
DataPoint set to visible.	System	08 Jan 2021 18:02:08

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12:30'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '8 Jan 2021 12:30'	System	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'ONCE'	System	08 Jan 2021 18:02:50

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 18:02:50



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:04:49

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:04:49

**US3522227**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12:10'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:04:49

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '8 Jan 2021 12:10'	System	08 Jan 2021 18:04:49

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:57:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:00

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:57:05**

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:00

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12:15'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:00

US3522227

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:57:05**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '8 Jan 2021 12:15'	System	08 Jan 2021 18:05:00



US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:06

US3522227

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'I'	System	08 Jan 2021 18:05:06

US3522227

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:54

US3522227

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 04:58:55
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'call made out of window in error' (Site from System).	Alandra White (b) (4) (b) (4)	18 Feb 2021 18:13:09
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 01:13:45
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 20:08:54

US3522227

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:54

US3522227

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
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)	14 Jan 2021 20:08:54

US3522227

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:08:57

US3522227

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'I'	System	14 Jan 2021 20:08:57



US3522227

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '1'	System	14 Jan 2021 20:08:57
DataPoint set to visible.	System	14 Jan 2021 20:08:57

US3522227

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:04

US3522227

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:04

US3522227

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:04

**US3522227**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'OLD29'	System	05 Feb 2021 17:26:04

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37



US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12:17'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '5 Feb 2021 12:17'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '58'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'bpm'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '18'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37



US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'breaths/min'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '138'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '75'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37



US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12:50'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '5 Feb 2021 12:50'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '52'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'bpm'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '18'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37



US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'breaths/min'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '133'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '87'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	05 Feb 2021 18:25:37

US3522227

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:13

US3522227

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:13

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:29



US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mRNA-1273'	System	05 Feb 2021 17:26:29
DataPoint set to visible.	System	14 Jan 2021 20:08:57

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12:20'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '5 Feb 2021 12:20'	System	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'ONCE'	System	05 Feb 2021 17:26:29



US3522227

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 17:26:29

US3522227

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:23:12

US3522227

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'I'	System	05 Feb 2021 18:23:12

US3522227

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:28:56

US3522227

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:28:56

US3522227

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:28:56

US3522227

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:28:56

US3522227

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:29:00



**US3522227**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'I'	System	12 Feb 2021 19:29:00

**US3522227**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:07:54

US3522227

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:07:54

US3522227

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:07:54

US3522227

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'OLD57'	System	05 Mar 2021 17:07:54

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '12:09'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33



US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '5 Mar 2021 12:09'	System	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '50'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'bpm'	System	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '15'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'breaths/min'	System	05 Mar 2021 17:10:33



US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '135'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '67'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered 'mmHg'	System	05 Mar 2021 17:10:33

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07

US3522227

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07

US3522227

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:40

US3522227

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:40



US3522227

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:23:26

US3522227

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:23:26

US3522227

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:03:30
User entered '12:20'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:23:26

**US3522227**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:01:07
User entered '5 Mar 2021 12:20'	System	05 Mar 2021 17:23:26

US3522227

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:57:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:03:48
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:42:43

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:01
User entered 'USA-US131-2021-mRNA-1273-P301000002'	System	11 Jan 2021 16:14:57
User entered 'New'	(b) (4), (b) (6)	11 Jan 2021 16:14:57

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 18:42:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 18:42:42
	(b) (4)	
Data point term sent to Coder	System	08 Jan 2021 17:47:11
User entered 'Atrial fibrillation exacerbation'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48



US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	08 Jan 2021 17:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:47:26
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Jan 2021 17:46:48
User entered '22:30'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 17:47:26
User entered '6 Jan 2021 22:30'	System	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	08 Jan 2021 17:47:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:47:26
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	08 Jan 2021 17:46:48
User entered '20:00'	(b) (4), (b) (6)	08 Jan 2021 17:46:48



**US3522227**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 17:47:26
User entered '7 Jan 2021 20:00'	System	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	08 Jan 2021 17:47:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:47:41
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	08 Jan 2021 17:47:26
User entered 'No (N)'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Jan 2021 17:47:26
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Jan 2021 17:47:26
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:47:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Jan 2021 17:46:48
User entered '0'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered '6 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:47:26
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered '7 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:47:26
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:46:48



US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 10 Jun 2021 07:57:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:53:27
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	22 Jan 2021 13:45:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Jan 2021 17:50:12
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 15:35:08
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Jan 2021 17:46:48



US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	05 Feb 2021 17:33:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 17:33:41
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Feb 2021 17:33:23
User entered '0'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of ATRIAL FIBRILLATION. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:10:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of ATRIAL FIBRILLATION. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' answered with 'Patient had no new meds added or used' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:33:58
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Feb 2021 17:33:23
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)	03 Feb 2021 18:46:04
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)	01 Feb 2021 21:22:52

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of ATRIAL FIBRILLATION. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:45:45
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 07:48:33
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Feb 2021 17:29:53
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'No medical treatment procedures as afib had resolved' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:29:38
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:45:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:55:36
User entered '0'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:46:48

US3522227

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed 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) (4), (b) (6)	08 Feb 2021 19:01:58
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.' answered with 'no treatment other than diagnostics' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:34:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:04:32
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 'Laboratory results were present in the hospital discharge papers already sent' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 16:24:21
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 14:30:03

US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Hospital summary records sent' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 14:51:10
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)	25 Jan 2021 15:53:23
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 'Does not appear to be done per hospital records' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	22 Jan 2021 13:55:28
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)	15 Jan 2021 15:34:48
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 15:34:42
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)	15 Jan 2021 15:34:36



US3522227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:05

[Narrative](#)

Audit	User	Time (GMT)
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)	15 Jan 2021 15:34:30
User entered 'Pt was admitted to Observation floor at Beaumont for a HR ranging from 40-140. (related to hx of afib) .Pt had SOB and chest heaviness. He was admitted and all tests were negative. They told him to stop taking metformin. symptoms are no longer there and patient states he feels fine. he is following up with his PCP at VA.'	(b) (4), (b) (6)	08 Jan 2021 17:46:48

**US3522227**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 17:47:41
User entered '0'	System	08 Jan 2021 17:46:48

US3522227

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 10 Jun 2021 07:57:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 17:46:48

**US3522227**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 17:46:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 07:57:05**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:23
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 17:47:45

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 18:05:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:05:30
Data point term sent to Coder	System	19 Aug 2020 18:04:41
User entered 'Synthroid'	(b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Hypothyroidism'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0.075'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '2 on Sunday, 1 Monday through Saturday'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:04:10

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:04:10

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:04:10

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 18:06:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:06:28
Data point term sent to Coder	System	19 Aug 2020 18:05:44
User entered 'Pantoprazole'	(b) (4), (b) (6)	19 Aug 2020 18:05:21



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:05:21

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 18:05:21

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:05:21



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:05:21

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
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)	26 Aug 2020 11:53:49
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 11:53:49
Data point term sent to Coder	System	19 Aug 2020 18:09:55
User entered 'Metoprolol Tartrate'	(b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'High Blood Pressure'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '25'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 18:34:59
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 18:09:47
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:34:59
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:09:47



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:09:47

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:09:47

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 18:36:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:36:22
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	19 Aug 2020 18:35:08 19 Aug 2020 18:34:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:13:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:13:21
Data point term sent to Coder User entered 'Symbicort'	System (b) (4), (b) (6)	19 Aug 2020 18:11:59 19 Aug 2020 18:11:14

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:34:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 18:34:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:34:32
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:11:14
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'COPD' reason for change: Data Entry	(b) (4)	19 Aug 2020 18:34:32
Error	(b) (4), (b) (6)	
User entered 'Asthma'	(b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:28:32
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:14:43
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 07:46:44
User entered '160/4.5'	(b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:14:36
User entered 'puff (PUFF)'	(b) (4), (b) (6)	19 Aug 2020 18:11:14



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:11:14

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:11:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:11:14

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 00:27:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 00:27:14
Data point term sent to Coder	System	19 Aug 2020 18:13:04
User entered 'Tiotropium Bromide'	(b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:28

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:12:28

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:12:28

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:12:28

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:58:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:58:21
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 18:56:58
Data point term sent to Coder	System	19 Aug 2020 18:55:58
User entered 'Xarelto'	(b) (4), (b) (6)	19 Aug 2020 18:55:33



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:55:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 18:55:48
User entered 'Atrial fibrillation' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:55:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:55:33
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:56:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 18:56:00
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:56:00
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:55:33
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:33



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:55:33

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:55:33



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:55:33

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE, PRODUCTSYNONYM: PROSCAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 18:58:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:58:24
Data point term sent to Coder	System	19 Aug 2020 18:58:02
User entered 'Proscar'	(b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'BPH'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:14



**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:57:14

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:57:14

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN, PRODUCTSYNONYM: ZOCOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 18:58:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:58:24
Data point term sent to Coder	System	19 Aug 2020 18:58:04
User entered 'Zocor'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:57:58

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:57:58

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:57:58

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 19:00:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:00:26
Data point term sent to Coder	System	19 Aug 2020 18:59:08
User entered 'Flomax'	(b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'BPH'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0.4'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:58:52

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:58:52

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: BUTALBITAL;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: FIORICET - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Aug 2020 18:33:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:33:37
Data point term sent to Coder	System	25 Aug 2020 18:32:11
User entered 'FIORiCET' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 18:31:13
Data point term sent to Coder	System	19 Aug 2020 19:00:12
User entered 'Fiorcet'	(b) (4), (b) (6)	19 Aug 2020 18:59:42



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 18:31:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 18:31:13
User entered 'migraines' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 18:31:13
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:59:42
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:59:42

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:59:42



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:59:42

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 08:52:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 08:52:11
Data point term sent to Coder	System	19 Aug 2020 19:01:14
User entered 'Valium'	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Migraines'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:00:29



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:00:29

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:00:29

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 19:02:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:02:25
Data point term sent to Coder	System	19 Aug 2020 19:01:14
User entered 'Norco'	(b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Migraines'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:01:02

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:01:02

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 19:03:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:03:29
Data point term sent to Coder	System	19 Aug 2020 19:02:15
User entered 'Albuterol'	(b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:01:48

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:01:48

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:01:48

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: DOFETILIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 19:04:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:04:31
Data point term sent to Coder	System	19 Aug 2020 19:03:16
User entered 'Dofetilide'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 19:02:55



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Atrial fibrillation'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '500'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED]	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:02:55

**US3522227**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 19:02:55

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:02:55



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:02:55

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN HYDROCHLORIDE, PRODUCTSYNONYM: DITROPAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 19:05:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:05:23
Data point term sent to Coder	System	19 Aug 2020 19:04:17
User entered 'Ditropan'	(b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Overactive bladder'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '5'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:35



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:03:35

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:03:35

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:55:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:55:12
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:04:23
User entered 'Metformin'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'Morbid obesity/weight loss'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:04:22



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 17:51:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:04:22



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'UN Aug 2020' reason for change:	(b) (4), (b) (6)	08 Jan 2021 17:51:04
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User entered '2'	System	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User entered '1'	System	19 Aug 2020 19:04:22

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:42:08
User entered '804 (804)'	System	19 Aug 2020 19:04:22

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 22:00:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 22:00:23
Data point term sent to Coder	System	08 Oct 2020 13:54:58
User entered 'Flu Shot'	(b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Annual vaccine'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:57:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:57:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:57:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50



US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:54:50

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User entered empty.	System	08 Oct 2020 13:54:50

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User entered empty.	System	08 Oct 2020 13:54:50

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:57
User entered empty.	System	08 Oct 2020 13:54:50

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:09:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:09:32
Data point term sent to Coder	System	15 Oct 2020 17:08:39
User entered 'Flu Vaccine'	(b) (4), (b) (6)	15 Oct 2020 17:07:57



US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Flu'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57



US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:57

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:57:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User entered empty.	System	15 Oct 2020 17:07:57

US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User entered empty.	System	15 Oct 2020 17:07:57



US3522227

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:57:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:52:53
User entered empty.	System	15 Oct 2020 17:07:57

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 07:57:05**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:55:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:55:39

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:57:05**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:13

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Electrocardiography'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:13

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:13

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:57:05**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:13

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 07:57:05**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:42

US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'CT heart'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:42



US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:42

US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:56:42

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 07:57:05**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:57:12

US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:57:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Nuclear stress test'	(b) (4), (b) (6)	08 Jan 2021 17:57:12

US3522227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:57:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:57:12

US3522227

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 07:57:05**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:03:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:57:12

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'USA-US131-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Paul'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Kilgore'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) ,	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) '	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'MI'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:54:13
User entered 'US'	System	11 Jan 2021 16:15:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Feb 2021 19:02:20
User entered '3'	System	25 Jan 2021 15:57:19
User entered '2'	System	20 Jan 2021 20:58:30
User entered '1'	System	11 Jan 2021 16:15:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'USA-US131-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Paul'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Kilgore'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) ,	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) '	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'MI'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:54:13
User entered 'US'	System	11 Jan 2021 16:15:19

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Feb 2021 19:02:20
User entered '3'	System	25 Jan 2021 15:57:19
User entered '2'	System	20 Jan 2021 20:58:30
User entered '1'	System	11 Jan 2021 16:15:19

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 07:57:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '11/Jan/2021 11:15'	(b) (4) System	11 Jan 2021 16:15:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:57:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 20:54:13
User entered 'I'	(b) (4), (b) (6)	11 Jan 2021 16:15:19



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'USA-US131-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Paul'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Kilgore'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) ,	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) '	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'MI'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:54:13
User entered 'US'	System	11 Jan 2021 16:15:19

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Feb 2021 19:02:20
User entered '3'	System	25 Jan 2021 15:57:19
User entered '2'	System	20 Jan 2021 20:58:30
User entered '1'	System	11 Jan 2021 16:15:19



**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 07:57:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '20/Jan/2021 20:58'	(b) (4) System	20 Jan 2021 20:58:30

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:57:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:57:12
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 20:58:30

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'USA-US131-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Paul'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Kilgore'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) ,	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) '	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'MI'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6)'	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:54:13
User entered 'US'	System	11 Jan 2021 16:15:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Feb 2021 19:02:20
User entered '3'	System	25 Jan 2021 15:57:19
User entered '2'	System	20 Jan 2021 20:58:30
User entered '1'	System	11 Jan 2021 16:15:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:57:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '25/Jan/2021 15:57'	(b) (4) System	25 Jan 2021 15:57:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:57:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:04
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 15:57:19

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'USA-US131-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57



**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Yes (Y)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'No (N)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Paul'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'Kilgore'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) ,	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6) '	System	11 Jan 2021 16:14:57



US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered 'MI'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:15:10
User entered (b) (6)'	System	11 Jan 2021 16:14:57

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:54:13
User entered 'US'	System	11 Jan 2021 16:15:19

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Feb 2021 19:02:20
User entered '3'	System	25 Jan 2021 15:57:19
User entered '2'	System	20 Jan 2021 20:58:30
User entered '1'	System	11 Jan 2021 16:15:19

**US3522227**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 07:57:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
User entered '08/Feb/2021 14:02'	(b) (4) System	08 Feb 2021 19:02:20

US3522227

Folder: SAE USA-US131-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:57:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:40:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 19:03:04
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 19:02:20