

US3352297 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:12:18

All time stamps listed in this document are displayed in GMT

US3352297

**Form: Participant Creation**

**Data signed:** (b) (4) 28 Apr 2021 14:24:31

**Generated On: 09 Jun 2021 17:12:18**

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[Participant ID](#)

US3352297

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

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US3352297

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 01 SEP 2020

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

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Folder OID SCRN

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US3352297

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
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) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Date of Informed Consent (*dd MMM yyyy*) 01 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

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

Was this participant screened previously? Yes   
No

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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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) 28 Apr 2021 14:24:49

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	NOSE TRAUMA
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	TONSILLITIS (RECURRING)
Start date (dd MMM yyyy)	UN APR 1964
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 1964
Stop date completely unknown	False
Start Month and Year (derived)	APR 1964
Start Year (derived)	1964
Stop Month and Year (derived)	APR 1964
Stop Year (derived)	1964

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	FOOD ALLERGY - PEACH
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	EX-SMOKER (TOBACCO)
Start date (dd MMM yyyy)	UN DEC 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2020
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	SURGERY - RHINOPLASTY
Start date (dd MMM yyyy)	UN JUN 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 1984
Stop date completely unknown	False
Start Month and Year (derived)	JUN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JUN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	SURGERY - TONSILLECTOMY
Start date (dd MMM yyyy)	UN APR 1964
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 1964
Stop date completely unknown	False
Start Month and Year (derived)	APR 1964
Start Year (derived)	1964
Stop Month and Year (derived)	APR 1964
Stop Year (derived)	1964

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	SURGERY - FEMORAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN MAY 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2010
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2010
Start Year (derived)	2010
Stop Month and Year (derived)	MAY 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	LEFT HAND 1ST DIGIT NUMBNESS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Condition	LEFT HAND SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:10 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:10
Height ( <i>xxx.x</i> )	170.0 cm
Weight ( <i>xxx.x</i> )	79.9 kg
BMI ( <i>xxx.x</i> )	27.64706 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) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

1 SEP 2020

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

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US3352297

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 14:24:49

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

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**Specify**

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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) 28 Apr 2021 14:24:49

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	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) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110585

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

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

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

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

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

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:10 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:10
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:49 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:49
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	57 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 11:19 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 11:19

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) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	1 SEP 2020
Collection time ( <i>00:00-23:59</i> )	10:50 (24 HR)
Collection date and time (derived)	1 SEP 2020 10:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Collection date ( <i>dd MMM yyyy</i> )			1 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	1 SEP 2020 10:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**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 97.5 °F

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

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

PC Time Stamp 01 SEP 2020 11:59

PC Open Date & Time 01 SEP 2020 11:39

PC Close Date & Time 01 SEP 2020 14:09

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.6 °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 01 SEP 2020 15:22  
PC Open Date & Time 01 SEP 2020 15:04  
PC Close Date & Time 02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp 02 SEP 2020 19:37

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 SEP 2020 21:38
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

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

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PC Time Stamp	04 SEP 2020 19:04
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 08:16
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.0 °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 06 SEP 2020 17:37

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.2 °F

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

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

PC Time Stamp 07 SEP 2020 19:10

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

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

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

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

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

- Yes
- No

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

- Yes
- No

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

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

PC Time Stamp

01 SEP 2020 12:00

PC Open Date & Time

01 SEP 2020 11:39

PC Close Date & Time

01 SEP 2020 14:09

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**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

01 SEP 2020 15:23

PC Open Date & Time

01 SEP 2020 15:04

PC Close Date & Time

02 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

02 SEP 2020 19:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

03 SEP 2020 21:41

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

04 SEP 2020 19:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 5

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

Please select one response below

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

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

- Yes
- No

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

06 SEP 2020 17:39

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**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

07 SEP 2020 19:11

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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

No

Yes

PC Time stamp	01 SEP 2020 12:01
PC Open Date & Time	01 SEP 2020 11:39
PC Close Date & Time	01 SEP 2020 14:09

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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

No

Yes

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PC Time stamp	01 SEP 2020 15:24
PC Open Date & Time	01 SEP 2020 15:04
PC Close Date & Time	02 SEP 2020 11:59

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US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 19:39
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

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US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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	Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 21:42
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

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US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 19:07
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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Yes

---

PC Time stamp

---

PC Open Date & Time

05 SEP 2020 12:00

---

PC Close Date & Time

06 SEP 2020 11:59

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US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 17:41
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

---

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 19:12
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

---

US3352297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 29 SEP 2020

---

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

---

Folder OID VISIT2

---

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:56 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:56
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	54 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:08 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:08
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	49 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3352297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

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.*

---

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

Was study treatment given? Yes  No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 09:38

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

US3352297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 SEP 2020

---

Collection time (*00:00-23:59*) 09:13 (24 HR)

---

Collection date and time (derived) 29 SEP 2020 09:13

---

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Collection date ( <i>dd MMM yyyy</i> )			29 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	29 SEP 2020 09:05
Nasopharyngeal Swab 2	No		

---

US3352297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

PC Time Stamp 29 SEP 2020 10:11

PC Open Date & Time 29 SEP 2020 09:58

PC Close Date & Time 29 SEP 2020 12:28

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp 29 SEP 2020 21:42  
PC Open Date & Time 29 SEP 2020 13:23  
PC Close Date & Time 30 SEP 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	01 OCT 2020 03:13
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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

PC Time Stamp	02 OCT 2020 00:01
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 OCT 2020 18:05
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

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

PC Time Stamp	03 OCT 2020 18:03
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**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** 98.7 °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 04 OCT 2020 19:02

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 OCT 2020 16:46
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

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

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

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

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

- Yes
- No

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

- Yes
- No

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

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

PC Time Stamp	29 SEP 2020 10:11
PC Open Date & Time	29 SEP 2020 09:58
PC Close Date & Time	29 SEP 2020 12:28

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

29 SEP 2020 21:43

PC Open Date & Time

29 SEP 2020 13:23

PC Close Date & Time

30 SEP 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

01 OCT 2020 03:14

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

02 OCT 2020 00:02

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

02 OCT 2020 18:06

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

03 OCT 2020 18:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

04 OCT 2020 19:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

05 OCT 2020 16:47

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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

No

Yes

---

PC Time stamp	29 SEP 2020 10:12
PC Open Date & Time	29 SEP 2020 09:58
PC Close Date & Time	29 SEP 2020 12:28

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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

No   
Yes

---

PC Time stamp	29 SEP 2020 21:44
PC Open Date & Time	29 SEP 2020 13:23
PC Close Date & Time	30 SEP 2020 11:59

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 03:14
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 00:03
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 18:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	03 OCT 2020 18:06
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 19:04
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

---

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

---

	Yes <input type="checkbox"/>
PC Time stamp	05 OCT 2020 16:47
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

---

US3352297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 27 OCT 2020

---

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

---

Folder OID VISIT3

---

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 27 OCT 2020

Time of assessment (00:00-23:59) 08:13 (24 HR)

Vital Signs Date and Time (derived) 27 OCT 2020 08:13

Temperature (xxx.x) 37.0 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (xxx) 65 beats/min

Pulse units BPM

Respiratory Rate (xxx) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 138 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 80 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3352297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

27 OCT 2020

---

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

---

US3352297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	27 OCT 2020
Collection time ( <i>00:00-23:59</i> )	08:25 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:25

---

US3352297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 11:54:51
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 06:27:31
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 15 NOV 2020 07:16:34

Patient Cloud Open Date & Time 15 NOV 2020 00:01

Patient Cloud Close Date & Time 19 NOV 2020 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 82

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 28 NOV 2020 13:33:20

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 10 DEC 2020 07:39:12

Patient Cloud Open Date & Time 10 DEC 2020 00:01

Patient Cloud Close Date & Time 14 DEC 2020 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 20:56:11
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 07:01:18
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 01 JAN 2021 09:34:20

Patient Cloud Open Date & Time 31 DEC 2020 00:01

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

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 12:14:37
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 15 JAN 2021 12:14:02

Patient Cloud Open Date & Time 14 JAN 2021 00:01

Patient Cloud Close Date & Time 18 JAN 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 JAN 2021 14:39:06
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 28 JAN 2021 05:18:44

Patient Cloud Open Date & Time 28 JAN 2021 00:01

Patient Cloud Close Date & Time 01 FEB 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 04 FEB 2021 04:34:32

Patient Cloud Open Date & Time 04 FEB 2021 00:01

Patient Cloud Close Date & Time 08 FEB 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 08:39:24
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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 <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 FEB 2021 11:24:01
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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	01 MAR 2021 14:12:57
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 02:17:43
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 09:29:48
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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 20 MAR 2021 15:34:26

Patient Cloud Open Date & Time 18 MAR 2021 00:01

Patient Cloud Close Date & Time 22 MAR 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 APR 2021 00:09:02
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 05:29:43
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 15 APR 2021 00:01

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[Patient Cloud Close Date & Time](#) 19 APR 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 05:58:57
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 264

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

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07 JUN 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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

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[Patient Cloud Close Date & Time](#) 05 JUL 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 15 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#) 19 JUL 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 341

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

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

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09 AUG 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 19 AUG 2021 00:01

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

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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°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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 14 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 18 OCT 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#) 08 NOV 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 446

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 06 DEC 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 13 DEC 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 20 DEC 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 481

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 495

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JAN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

US3352297

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**Generated On: 09 Jun 2021 17:12:18**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

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Date and time of submission

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17 FEB 2022 00:01

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21 FEB 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

US3352297

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 24 FEB 2022 00:01

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

US3352297

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

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**Generated On: 09 Jun 2021 17:12:18**

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Date and time of submission

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03 MAR 2022 00:01

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07 MAR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Date and time of submission

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10 MAR 2022 00:01

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14 MAR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3352297

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

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**Generated On: 09 Jun 2021 17:12:18**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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21 MAR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

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I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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28 MAR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:12:18**

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[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

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11 APR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

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[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

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

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#) 06 JUN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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°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

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

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08 AUG 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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18 AUG 2022 00:01

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22 AUG 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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25 AUG 2022 00:01

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29 AUG 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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01 SEP 2022 00:01

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05 SEP 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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08 SEP 2022 00:01

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12 SEP 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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15 SEP 2022 00:01

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19 SEP 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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29 SEP 2022 00:01

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03 OCT 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Date and time of submission

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06 OCT 2022 00:01

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10 OCT 2022 23:59

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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13 OCT 2022 00:01

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17 OCT 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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[Patient Cloud Open Date & Time](#) 20 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 24 OCT 2022 23:59

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US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**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

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

---

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59

---

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )
- 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

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

---

US3352297

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:12:18

---

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		01 MAR 2021 14:12:41

---

US3352297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 NOV 2020

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 DEC 2020

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 FEB 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 MAR 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID VISIT4

---

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:00 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 11:00
Temperature ( <i>xxx.x</i> )	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	55 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352297

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

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.*

---

US3352297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 16 MAR 2021

---

Collection time (*00:00-23:59*) 11:07 (24 HR)

---

Collection date and time (derived) 16 MAR 2021 11:07

---

US3352297

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:50

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 APR 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

---

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* \_\_\_\_\_

---

US3352297

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3352297

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:12:18

---

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

---

US3352297

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:12:18

---

Generate Next COVID-19 Assessment

Yes

No

---

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 JAN 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID UNBLND\_DECIDE

---

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

Date of updated informed consent ( <i>dd MMM yyyy</i> )	16 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> )	16 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

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

---

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

---

---

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

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)	16 JAN 2021
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 14:08
Temperature (xxx.x)	37.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

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)	16 JAN 2021
Time of assessment (00:00-23:59)	15:14 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 15:14
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 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)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

---

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.*

---

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

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) 16 JAN 2021

What was the treatment time? (00:00-23:59) 14:44 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 14:44

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

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 16 JAN 2021

---

Collection time (*00:00-23:59*) 14:20 (24 HR)

---

Collection date and time (derived) 16 JAN 2021 14:20

---

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 16 JAN 2021

---

Collection time (*00:00 - 23:59*) 14:13

---

Collection Date and Time (derived) 16 JAN 2021 14:13

---

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 JAN 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

---

US3352297

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 13 FEB 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID OLD29

---

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	08:25 (24 HR)
Vital Signs Date and Time (derived)	13 FEB 2021 08:25
Temperature ( <i>xxx.x</i> )	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	56 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	77 mmHg
Diastolic Blood Pressure units	MMHG

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	09:51 (24 HR)
Vital Signs Date and Time (derived)	13 FEB 2021 09:51
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	56 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG

US3352297

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

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.*

---

US3352297

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify \_\_\_\_\_

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 13 FEB 2021

What was the treatment time? (00:00-23:59) 09:20 (24 HR)

Treatment Date and Time (derived) 13 FEB 2021 09:20

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

US3352297

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 FEB 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3352297

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 14:24:49

Generated On: 09 Jun 2021 17:12:18

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3352297

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 MAR 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID OLD57

---

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:00 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 11:00
Temperature ( <i>xxx.x</i> )	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	55 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3352297

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

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.*

---

US3352297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 16 MAR 2021

---

Collection time (*00:00-23:59*) 11:07 (24 HR)

---

Collection date and time (derived) 16 MAR 2021 11:07

---

US3352297

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

AEID USA-US066-2021-MRNA-1273-P30  
1000005

Adverse event LEFT HAND TRAUMA

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 20 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 18 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 20 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 23 JAN 2021

Admitted to ICU? Yes   
No   
Unknown

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None False

---

Concomitant Medication True

---

Concomitant Procedure True

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

SUBJECT WENT TO THE  
HOSPITAL AFTER AN INJURY  
TO HIS LEFT HAND. HE WAS  
POWERWASHING THE ROOF OF  
HIS CAR WHEN HIS LEFT HAND  
SLIPPED AND THE  
POWERWASHER GUN NOZZLE  
HIT THE BACK OF HIS LEFT  
HAND.

---

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

---

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

---

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

---

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication CARDIAC PROFHYLAXIS

Dose per administration 81

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 1998

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication CEPHALEXIN

Prophylaxis Yes   
No

Indication LEFT HAND REPAIR

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

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 22 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 16 FEB 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication AMOX-CLAV

Prophylaxis Yes   
No

Indication LEFT HAND REPAIR

Dose per administration 875/125

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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US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 22 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 27 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication BOOSTRIX

Prophylaxis Yes   
No

Indication LEFT HAND TRAUMA

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 20 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 20 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication ZOSYN

Prophylaxis Yes   
No

Indication LEFT HAND TRAUMA

Dose per administration 3.375

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 20 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 21 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes   
No

Indication LEFT HAND TRAUMA

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 20 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 21 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Name of Medication POLYSPORIN

Prophylaxis Yes   
No

Indication LEFT HAND TRAUMA

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify APPLICATION

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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US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

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*) 30 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 18 FEB 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 14:24:31

Generated On: 09 Jun 2021 17:12:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 JAN 2021	LEFT HAND REPAIR	Adverse Event	
20 JAN 2021	XRAY HAND LEFT LATERAL AND OBLIQUE	Adverse Event	

US3352297

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:12:18

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

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

SAEID	USA-US066-2021-MRNA-1273-P301000005
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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

SAEID USA-US066-2021-MRNA-1273-P30  
1000005

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name HOWARD

Investigator's Last Name SCHWARTZ

Site Address: Street 7265 SHERIDAN STREET SUITE  
210

Site Address: City PEMBROKE PINES

Site Address: State FL

Site Address: Postal Code 33024

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 27/JAN/2021 14:23

**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

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

SAEID USA-US066-2021-MRNA-1273-P30  
1000005

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name HOWARD

Investigator's Last Name SCHWARTZ

Site Address: Street 7265 SHERIDAN STREET SUITE  
210

Site Address: City PEMBROKE PINES

Site Address: State FL

Site Address: Postal Code 33024

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 08/FEB/2021 09:05

**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.** True

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

SAEID USA-US066-2021-MRNA-1273-P30  
1000005

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name HOWARD

Investigator's Last Name SCHWARTZ

Site Address: Street 7265 SHERIDAN STREET SUITE  
210

Site Address: City PEMBROKE PINES

Site Address: State FL

Site Address: Postal Code 33024

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 16/FEB/2021 14:08

**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

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

SAEID	USA-US066-2021-MRNA-1273-P301000005
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	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/MAR/2021 08:32
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	True

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 14:24:32

Generated On: 09 Jun 2021 17:12:18

SAEID USA-US066-2021-MRNA-1273-P30  
1000005

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name HOWARD

Investigator's Last Name SCHWARTZ

Site Address: Street 7265 SHERIDAN STREET SUITE  
210

Site Address: City PEMBROKE PINES

Site Address: State FL

Site Address: Postal Code 33024

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 18/MAR/2021 12:14

**Check box to submit initial and significant follow-up concerning  
this SAE. By checking this box I hereby confirm all relevant data  
has been entered and reviewed to the best of my knowledge.** True

Audit

US3352297 (Prod: Research Centers of America - ERG)

US3352297

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:12:18**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:26:58
User entered 'US3352297'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:53

US3352297

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:21:37

US3352297

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:17
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:54

US3352297

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 17:21:37

US3352297

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'SCRN'	System	01 Sep 2020 17:21:37

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:56

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '62'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'YEARS'	System	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '62'	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered 'Male (M)'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:12:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:35:28
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:14

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered '01 Sep 2020'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Sep 2020'	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2020'	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered 'Amendment 3 (3)'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered empty.	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered empty.	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:36:12
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:54

US3352297

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:12:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1'	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:12:18

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:38:56
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:52:49

US3352297

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:12:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:39:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:22:23

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:23:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:23:55
Data point term sent to Coder	System	01 Sep 2020 17:22:49
User entered 'MYOPIA'	(b) (4), (b) (6)	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN UNK 1968'	(b) (4), (b) (6)	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1968'	System	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1968'	System	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered empty.	System	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered empty.	System	01 Sep 2020 17:22:48

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Nasal injury, LLT: Nose injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:49:41
Data point term sent to Coder	System	01 Sep 2020 17:23:52
User entered 'NOSE TRAUMA'	(b) (4), (b) (6)	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User closed query 'Per DM CLR: Please review the status of this condition as the effects of the NOSE TRAUMA may be longer but the condition itself is not' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:43:13
User entered 'UN UNK 1984' reason for change: Data Entry Error	Matthew Muniz (b) (4)	29 Oct 2020 18:49:28
Query 'Per DM CLR: Please review the status of this condition as the effects of the NOSE TRAUMA may be longer but the condition itself is not' answered with 'data updated' (Site from DM).	Matthew Muniz (b) (4)	29 Oct 2020 18:49:14
User entered 'UN Jun 1984' reason for change: Data Entry Error	Matthew Muniz (b) (4)	29 Oct 2020 18:48:57
User opened query 'Per DM CLR: Please review the status of this condition as the effects of the NOSE TRAUMA may be longer but the condition itself is not' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:01:41
User entered 'UN Jun 1970' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 17:26:33
User entered 'UN UNK 1970'	(b) (4), (b) (6)	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 07) was reported (UN JUN 1984-UN JUN 1984). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:43:15
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	29 Oct 2020 18:49:28
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 07) was reported (UN JUN 1984-UN JUN 1984). Update eCRF as appropriate.' answered with 'data updated' (Site from DM).	Matthew Muniz (b) (4)	29 Oct 2020 18:49:17
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	29 Oct 2020 18:48:57
Query 'Per DM CLR: Please review the status of this condition as the effects of the NOSE TRAUMA may be longer but the condition itself is not.' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:01:32
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 07) was reported (UN JUN 1984-UN JUN 1984). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:01:23
User opened query 'Per DM CLR: Please review the status of this condition as the effects of the NOSE TRAUMA may be longer but the condition itself is not.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:00:50
User entered 'UN UNK 1984'	(b) (4), (b) (6)	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1984'	System	29 Oct 2020 18:49:28
User entered 'Jun 1984'	System	29 Oct 2020 18:48:57
User entered 'Jun 1970'	System	01 Sep 2020 17:26:33
User entered 'Jan 1970'	System	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1984'	System	29 Oct 2020 18:48:57
User entered '1970'	System	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1984'	System	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1984'	System	01 Sep 2020 17:23:22

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis recurrent - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:25:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:25:49
Data point term sent to Coder	System	01 Sep 2020 17:24:54
User entered 'TONSILLITIS (RECURRING)'	(b) (4), (b) (6)	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Apr 1964'	(b) (4), (b) (6)	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Apr 1964'	(b) (4), (b) (6)	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Apr 1964'	System	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1964'	System	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Apr 1964'	System	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1964'	System	01 Sep 2020 17:23:54

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Femoral hernias, PT: Femoral hernia, LLT: Femoral hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:25:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:25:49
Data point term sent to Coder	System	01 Sep 2020 17:24:55
User entered 'FEMORAL HERNIA'	(b) (4), (b) (6)	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN May 2010'	(b) (4), (b) (6)	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN May 2010'	(b) (4), (b) (6)	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'May 2010'	System	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2010'	System	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'May 2010'	System	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2010'	System	01 Sep 2020 17:24:20

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:50:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:50:43
Data point term sent to Coder	System	01 Sep 2020 17:24:56
User entered 'FOOD ALLERGY - PEACH'	(b) (4), (b) (6)	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN UNK 1972'	(b) (4), (b) (6)	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1972'	System	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1972'	System	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered empty.	System	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered empty.	System	01 Sep 2020 17:24:34

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Social circumstances, HLG: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-tobacco user - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 17:26:53
Data point term sent to Coder	System	01 Sep 2020 17:25:59
User entered 'EX-SMOKER (TOBACCO)'	(b) (4), (b) (6)	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Dec 2014'	(b) (4), (b) (6)	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN UNK 2020'	(b) (4), (b) (6)	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Dec 2014'	System	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2014'	System	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 2020'	System	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2020'	System	01 Sep 2020 17:25:07

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Rhinoplasty, LLT: Rhinoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:12:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:12:38
Data point term sent to Coder	System	01 Sep 2020 17:26:00
User entered 'SURGERY - RHINOPLASTY'	(b) (4), (b) (6)	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Jun 1984'	(b) (4), (b) (6)	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Jun 1984'	(b) (4), (b) (6)	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jun 1984'	System	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1984'	System	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jun 1984'	System	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1984'	System	01 Sep 2020 17:25:49

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:36:48
Data point term sent to Coder	System	01 Sep 2020 17:35:24
User entered 'SURGERY - TONSILLECTOMY'	(b) (4), (b) (6)	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Apr 1964'	(b) (4), (b) (6)	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN Apr 1964'	(b) (4), (b) (6)	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Apr 1964'	System	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1964'	System	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Apr 1964'	System	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1964'	System	01 Sep 2020 17:34:25

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Femoral hernia repair, LLT: Femoral hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:23:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:23:43
Data point term sent to Coder	System	01 Sep 2020 17:35:25
User entered 'SURGERY - FEMORAL HERNIA REPAIR'	(b) (4), (b) (6)	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN May 2010'	(b) (4), (b) (6)	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'UN May 2010'	(b) (4), (b) (6)	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'May 2010'	System	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2010'	System	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'May 2010'	System	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '2010'	System	01 Sep 2020 17:35:22

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness in fingers - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 08:52:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 08:52:45
Data point term sent to Coder	System	11 Feb 2021 20:31:10
User entered 'Left hand 1st digit numbness'	Surisaday Mederos (b) (4)	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Feb 2021 20:31:04
User entered 'UN UNK 1995' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	11 Feb 2021 20:31:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Feb 2021 20:30:41
User entered 'un 1995' (non-conformant).	Surisaday Mederos (b) (4)	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	Surisaday Mederos (b) (4)	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered empty.	Surisaday Mederos (b) (4)	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	Surisaday Mederos (b) (4)	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1995'	System	11 Feb 2021 20:31:04
User entered empty.	System	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1995'	System	11 Feb 2021 20:31:04
User entered empty.	System	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered empty.	System	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered empty.	System	11 Feb 2021 20:30:41

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Hand operation - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 20:34:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 20:34:05
Data point term sent to Coder	System	11 Feb 2021 20:33:13
User entered 'Left Hand Surgery'	Surisaday Mederos (b) (4)	11 Feb 2021 20:32:28
	(b) (4)	

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'un UNK 1995'	Surisaday Mederos (b) (4)	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	Surisaday Mederos (b) (4)	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'No (N)'	Surisaday Mederos (b) (4)	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered 'un UNK 1995'	Surisaday Mederos (b) (4)	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:16
User entered '0'	Surisaday Mederos (b) (4)	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1995'	System	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1995'	System	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'Jan 1995'	System	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:12:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1995'	System	11 Feb 2021 20:32:28

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered '10:10'	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '1 Sep 2020 10:10'	System	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered '170.0' cm	(b) (4), (b) (6)	01 Sep 2020 17:36:23
DataPoint set to visible.	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered '79.9' kg	(b) (4), (b) (6)	01 Sep 2020 17:36:23
DataPoint set to visible.	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered '27.64706'	System	01 Sep 2020 17:36:23
DataPoint set to visible.	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'kg/m2'	System	01 Sep 2020 17:36:23
DataPoint set to visible.	System	01 Sep 2020 15:53:11

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'bpm'	System	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'breaths/min'	System	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'mmHg'	System	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User entered 'mmHg'	System	01 Sep 2020 17:36:23

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56

US3352297

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56

US3352297

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:36:33

US3352297

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:44:51
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:36:33

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

**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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

**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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

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)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:12:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:03
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:37:20

US3352297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:37:28

US3352297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:31
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:37:28

US3352297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 17:37:28

US3352297

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'VISIT1'	System	01 Sep 2020 17:37:28

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:55:10

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered '110585'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:55:10

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:55:10

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

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)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:42

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

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)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:42

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:42

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:42

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:37:42

US3352297

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:12:18

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:45:59
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:36
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	05 Nov 2020 18:58:41
User entered 'No (N)'	Matthew Muniz (b) (4)	05 Nov 2020 18:58:36
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:16:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:53:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:53:20

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '10:10'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered '1 Sep 2020 10:10'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '36.8' C	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '60'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'bpm'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '16'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'breaths/min'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '126'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'mmHg'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '72'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'mmHg'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:54:40
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:51:13
User entered '11:49'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered '1 Sep 2020 11:49'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '36.6' C	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '57'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'bpm'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '15'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'breaths/min'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '123'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'mmHg'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:10
User entered '75'	(b) (4), (b) (6)	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'mmHg'	System	01 Sep 2020 17:38:51

US3352297

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:19
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:38:57

US3352297

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:19
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:38:57

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered empty.	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered empty.	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered '01 Sep 2020'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered '11:19'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered '01 Sep 2020 11:19'	System	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered 'Left Arm (LEFT ARM)'	Sara Gomez (b) (4) (b) (4)	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:47:27
User entered 'ONCE'	System	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 15:53:48

US3352297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:39:15

US3352297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:18
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:39:15

US3352297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:18
User entered '10:50'	(b) (4), (b) (6)	01 Sep 2020 17:39:15

US3352297

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered '1 Sep 2020 10:50'	System	01 Sep 2020 17:39:15

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:27
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:27
User entered '10:45'	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered '1 Sep 2020 10:45'	System	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:27
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:27
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered empty.	System	01 Sep 2020 17:39:31

US3352297

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:48:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:21:28

US3352297

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:55:49
User entered '1'	System	01 Sep 2020 17:21:28

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T11:57:48', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b09a07e3-8ac5-46f0-bcce-9bcc426d927e'	System	01 Sep 2020 15:59:53
User entered 'Yes (Y)'	System	01 Sep 2020 15:59:53

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T11:59:26', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b09a07e3-8ac5-46f0-bcce-9bcc426d927e'	System	01 Sep 2020 15:59:53
User entered '97.5'	System	01 Sep 2020 15:59:53

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T11:59:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b09a07e3-8ac5-46f0-bcce-9bcc426d927e'	System	01 Sep 2020 15:59:53
User entered 'No (N)'	System	01 Sep 2020 15:59:53

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T11:59:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b09a07e3-8ac5-46f0-bcce-9bcc426d927e'	System	01 Sep 2020 15:59:53
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 15:59:53

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 11:39'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 14:09'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:21:43', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '356678cb-9da5-45e2-b30d-b4fbafcab0e'	System	01 Sep 2020 19:22:20
User entered 'Yes (Y)'	System	01 Sep 2020 19:22:20

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:21:50', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '356678cb-9da5-45e2-b30d-b4fbafcab0e'	System	01 Sep 2020 19:22:20
User entered '97.6'	System	01 Sep 2020 19:22:20

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:22:03', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '356678cb-9da5-45e2-b30d-b4fbafcab0e'	System	01 Sep 2020 19:22:20
User entered 'No (N)'	System	01 Sep 2020 19:22:20

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:22:15', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '356678cb-9da5-45e2-b30d-b4fbafcabc0e'	System	01 Sep 2020 19:22:20
User entered '01 Sep 2020 15:22'	System	01 Sep 2020 19:22:20

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 15:04'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 2'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:37:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ede28a7a-cfe0-409e-8de6-7bd145f210a6'	System	02 Sep 2020 23:37:57
User entered 'Yes (Y)'	System	02 Sep 2020 23:37:57

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:37:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ede28a7a-cfe0-409e-8de6-7bd145f210a6'	System	02 Sep 2020 23:37:57
User entered '97.2'	System	02 Sep 2020 23:37:57

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:37:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ede28a7a-cfe0-409e-8de6-7bd145f210a6'	System	02 Sep 2020 23:37:57
User entered 'No (N)'	System	02 Sep 2020 23:37:57

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:37:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ede28a7a-cfe0-409e-8de6-7bd145f210a6'	System	02 Sep 2020 23:37:57
User entered '02 Sep 2020 19:37'	System	02 Sep 2020 23:37:57

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 3'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:37:31', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '281cdc47-d0de-4b9e-8c0e-5ba8fb7b9d92'	System	04 Sep 2020 01:38:59
User entered 'Yes (Y)'	System	04 Sep 2020 01:38:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:37:59', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '281cdc47-d0de-4b9e-8c0e-5ba8fb7b9d92'	System	04 Sep 2020 01:38:59
User entered '96.8'	System	04 Sep 2020 01:38:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:38:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '281cdc47-d0de-4b9e-8c0e-5ba8fb7b9d92'	System	04 Sep 2020 01:38:59
User entered 'No (N)'	System	04 Sep 2020 01:38:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:38:56', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '281cdc47-d0de-4b9e-8c0e-5ba8fb7b9d92'	System	04 Sep 2020 01:38:59
User entered '03 Sep 2020 21:38'	System	04 Sep 2020 01:38:59

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 4'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:03:30', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '24347381-6cd8-4137-8ec9-cfa345d02ae1'	System	04 Sep 2020 23:04:09
User entered 'Yes (Y)'	System	04 Sep 2020 23:04:09

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:03:44', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '24347381-6cd8-4137-8ec9-cfa345d02ae1'	System	04 Sep 2020 23:04:09
User entered '96.8'	System	04 Sep 2020 23:04:09

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:03:48', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '24347381-6cd8-4137-8ec9-cfa345d02ae1'	System	04 Sep 2020 23:04:09
User entered 'No (N)'	System	04 Sep 2020 23:04:09

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:04:06', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '24347381-6cd8-4137-8ec9-cfa345d02ae1'	System	04 Sep 2020 23:04:09
User entered '04 Sep 2020 19:04'	System	04 Sep 2020 23:04:09

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 5'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T08:16:25', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '99dbae14-25fb-433f-b466-08420e6c3f97'	System	06 Sep 2020 12:16:55
User entered 'Yes (Y)'	System	06 Sep 2020 12:16:55

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T08:16:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '99dbae14-25fb-433f-b466-08420e6c3f97'	System	06 Sep 2020 12:16:55
User entered '97.1'	System	06 Sep 2020 12:16:55

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T08:16:42', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '99dbae14-25fb-433f-b466-08420e6c3f97'	System	06 Sep 2020 12:16:55
User entered 'No (N)'	System	06 Sep 2020 12:16:55

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T08:16:51', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '99dbae14-25fb-433f-b466-08420e6c3f97'	System	06 Sep 2020 12:16:55
User entered '06 Sep 2020 08:16'	System	06 Sep 2020 12:16:55

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 6'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:36:57', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5e9516d4-7e0f-4b16-98dd-41e52cfdcc2b'	System	06 Sep 2020 21:37:33
User entered 'Yes (Y)'	System	06 Sep 2020 21:37:33

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:37:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5e9516d4-7e0f-4b16-98dd-41e52cfdcc2b'	System	06 Sep 2020 21:37:33
User entered '97.0'	System	06 Sep 2020 21:37:33

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:37:20', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5e9516d4-7e0f-4b16-98dd-41e52cfdcc2b'	System	06 Sep 2020 21:37:33
User entered 'No (N)'	System	06 Sep 2020 21:37:33

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:37:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5e9516d4-7e0f-4b16-98dd-41e52cfdcc2b'	System	06 Sep 2020 21:37:33
User entered '06 Sep 2020 17:37'	System	06 Sep 2020 21:37:33

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 7'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:10:09', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '62472e0e-49c2-4c8a-b322-3debd48d77a3'	System	07 Sep 2020 23:10:44
User entered 'Yes (Y)'	System	07 Sep 2020 23:10:44

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:10:16', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '62472e0e-49c2-4c8a-b322-3debd48d77a3'	System	07 Sep 2020 23:10:44
User entered '97.2'	System	07 Sep 2020 23:10:44

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:10:29', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '62472e0e-49c2-4c8a-b322-3debd48d77a3'	System	07 Sep 2020 23:10:44
User entered 'No (N)'	System	07 Sep 2020 23:10:44

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:10:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '62472e0e-49c2-4c8a-b322-3debd48d77a3'	System	07 Sep 2020 23:10:44
User entered '07 Sep 2020 19:10'	System	07 Sep 2020 23:10:44

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T11:59:59', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3c16dc27-11ec-466d-bdf5-56159ce78edd'	System	01 Sep 2020 16:00:48
User entered 'None (1)'	System	01 Sep 2020 16:00:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:00:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3c16dc27-11ec-466d-bdf5-56159ce78edd'	System	01 Sep 2020 16:00:48
User entered 'No (N)'	System	01 Sep 2020 16:00:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:00:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3c16dc27-11ec-466d-bdf5-56159ce78edd'	System	01 Sep 2020 16:00:48
User entered 'No (N)'	System	01 Sep 2020 16:00:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:00:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3c16dc27-11ec-466d-bdf5-56159ce78edd'	System	01 Sep 2020 16:00:48
User entered 'None (1)'	System	01 Sep 2020 16:00:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:00:35', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3c16dc27-11ec-466d-bdf5-56159ce78edd'	System	01 Sep 2020 16:00:48
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 16:00:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 11:39'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 14:09'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:22:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3b978342-d6ec-42e7-8657-8a7061f6ff7d'	System	01 Sep 2020 19:23:19
User entered 'None (1)'	System	01 Sep 2020 19:23:19

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:22:49', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3b978342-d6ec-42e7-8657-8a7061f6ff7d'	System	01 Sep 2020 19:23:19
User entered 'No (N)'	System	01 Sep 2020 19:23:19

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:22:56', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3b978342-d6ec-42e7-8657-8a7061f6ff7d'	System	01 Sep 2020 19:23:19
User entered 'No (N)'	System	01 Sep 2020 19:23:19

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:05', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3b978342-d6ec-42e7-8657-8a7061f6ff7d'	System	01 Sep 2020 19:23:19
User entered 'None (1)'	System	01 Sep 2020 19:23:19

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3b978342-d6ec-42e7-8657-8a7061f6ff7d'	System	01 Sep 2020 19:23:19
User entered '01 Sep 2020 15:23'	System	01 Sep 2020 19:23:19

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 15:04'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 2'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:38:05', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '750907d6-9df3-4a5f-898c-5e74f9b0f0a4'	System	02 Sep 2020 23:38:43
User entered 'None (1)'	System	02 Sep 2020 23:38:43

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:38:13', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '750907d6-9df3-4a5f-898c-5e74f9b0f0a4'	System	02 Sep 2020 23:38:43
User entered 'No (N)'	System	02 Sep 2020 23:38:43

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:38:26', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '750907d6-9df3-4a5f-898c-5e74f9b0f0a4'	System	02 Sep 2020 23:38:43
User entered 'No (N)'	System	02 Sep 2020 23:38:43

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:38:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '750907d6-9df3-4a5f-898c-5e74f9b0f0a4'	System	02 Sep 2020 23:38:43
User entered 'None (1)'	System	02 Sep 2020 23:38:43

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:38:40', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '750907d6-9df3-4a5f-898c-5e74f9b0f0a4'	System	02 Sep 2020 23:38:43
User entered '02 Sep 2020 19:38'	System	02 Sep 2020 23:38:43

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 3'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:39:13', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '16d6d52f-945e-4ba7-ac65-0acb3524a521'	System	04 Sep 2020 01:41:05
User entered 'None (1)'	System	04 Sep 2020 01:41:05

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:40:15', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '16d6d52f-945e-4ba7-ac65-0acb3524a521'	System	04 Sep 2020 01:41:05
User entered 'No (N)'	System	04 Sep 2020 01:41:05

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:40:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '16d6d52f-945e-4ba7-ac65-0acb3524a521'	System	04 Sep 2020 01:41:05
User entered 'No (N)'	System	04 Sep 2020 01:41:05

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:40:42', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '16d6d52f-945e-4ba7-ac65-0acb3524a521'	System	04 Sep 2020 01:41:05
User entered 'None (1)'	System	04 Sep 2020 01:41:05

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:01', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '16d6d52f-945e-4ba7-ac65-0acb3524a521'	System	04 Sep 2020 01:41:05
User entered '03 Sep 2020 21:41'	System	04 Sep 2020 01:41:05

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 4'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:04:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f4181875-d39a-4b95-81d2-c58f44daeac'	System	04 Sep 2020 23:05:26
User entered 'None (1)'	System	04 Sep 2020 23:05:26

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:04:34', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f4181875-d39a-4b95-81d2-c58f44daeac'	System	04 Sep 2020 23:05:26
User entered 'No (N)'	System	04 Sep 2020 23:05:26

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:04:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f4181875-d39a-4b95-81d2-c58f44daeac'	System	04 Sep 2020 23:05:26
User entered 'No (N)'	System	04 Sep 2020 23:05:26

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:05:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f4181875-d39a-4b95-81d2-c58f44daeac'	System	04 Sep 2020 23:05:26
User entered 'None (1)'	System	04 Sep 2020 23:05:26

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:05:23', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f4181875-d39a-4b95-81d2-c58f44daeac'	System	04 Sep 2020 23:05:26
User entered '04 Sep 2020 19:05'	System	04 Sep 2020 23:05:26

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 5'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 6'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:38:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ee416905-eb31-4a75-a55a-6d26b8d260bf'	System	06 Sep 2020 21:39:11
User entered 'None (1)'	System	06 Sep 2020 21:39:11

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:38:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ee416905-eb31-4a75-a55a-6d26b8d260bf'	System	06 Sep 2020 21:39:11
User entered 'No (N)'	System	06 Sep 2020 21:39:11

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:38:53', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ee416905-eb31-4a75-a55a-6d26b8d260bf'	System	06 Sep 2020 21:39:11
User entered 'No (N)'	System	06 Sep 2020 21:39:11

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:39:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ee416905-eb31-4a75-a55a-6d26b8d260bf'	System	06 Sep 2020 21:39:11
User entered 'None (1)'	System	06 Sep 2020 21:39:11

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:39:09', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ee416905-eb31-4a75-a55a-6d26b8d260bf'	System	06 Sep 2020 21:39:11
User entered '06 Sep 2020 17:39'	System	06 Sep 2020 21:39:11

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 7'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:10:56', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f69ca528-706d-4aa6-9e1f-b834d49e3d1e'	System	07 Sep 2020 23:12:03
User entered 'None (1)'	System	07 Sep 2020 23:12:03

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:11:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f69ca528-706d-4aa6-9e1f-b834d49e3d1e'	System	07 Sep 2020 23:12:03
User entered 'No (N)'	System	07 Sep 2020 23:12:03

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:11:30', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f69ca528-706d-4aa6-9e1f-b834d49e3d1e'	System	07 Sep 2020 23:12:03
User entered 'No (N)'	System	07 Sep 2020 23:12:03

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:11:42', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f69ca528-706d-4aa6-9e1f-b834d49e3d1e'	System	07 Sep 2020 23:12:03
User entered 'None (1)'	System	07 Sep 2020 23:12:03

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:11:56', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'f69ca528-706d-4aa6-9e1f-b834d49e3d1e' User entered '07 Sep 2020 19:11'	System	07 Sep 2020 23:12:03
	System	07 Sep 2020 23:12:03

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:00:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'None (0)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'None (0)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'None (0)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:18', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'None (0)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:22', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'None (0)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'None (0)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:34', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered 'No (N)'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T12:01:39', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3181518f-e51b-4b78-9e1e-e96f1c638527'	System	01 Sep 2020 16:02:29
User entered '01 Sep 2020 12:01'	System	01 Sep 2020 16:02:29

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 11:39'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 14:09'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:25', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'None (0)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:32', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'None (0)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:42', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'None (0)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'None (0)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:23:53', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'None (0)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:24:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'None (0)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:24:08', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered 'No (N)'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-01T15:24:14', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7e4d5da3-4c4e-47d9-ae52-ea509976fa4e'	System	01 Sep 2020 19:24:18
User entered '01 Sep 2020 15:24'	System	01 Sep 2020 19:24:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Sep 2020 15:04'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 2'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:38:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'None (0)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'None (0)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'None (0)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:39', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'None (0)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered 'No (N)'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-02T19:39:53', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1fbd3125-f211-4967-9ed2-75e8b2d4b9fe'	System	02 Sep 2020 23:39:56
User entered '02 Sep 2020 19:39'	System	02 Sep 2020 23:39:56

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 3'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'None (0)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:20', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'None (0)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'None (0)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'None (0)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:42', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'None (0)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'None (0)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:41:58', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered 'No (N)'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-03T21:42:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bdcda976-eab2-4dad-a554-2a69df69070b'	System	04 Sep 2020 01:42:07
User entered '03 Sep 2020 21:42'	System	04 Sep 2020 01:42:07

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 4'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:05:34', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'None (0)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:05:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'None (0)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:06:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'None (0)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:06:58', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'None (0)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:07:26', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'None (0)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:07:30', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'None (0)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:07:36', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered 'No (N)'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-04T19:07:43', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '914428fc-da64-4ead-b47b-e2e220d5bbab'	System	04 Sep 2020 23:07:46
User entered '04 Sep 2020 19:07'	System	04 Sep 2020 23:07:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 5'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 6'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:39:25', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'None (0)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:39:49', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'None (0)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:40:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'None (0)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:40:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'None (0)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:40:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'None (0)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:40:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'None (0)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:41:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee'	System	06 Sep 2020 21:41:12
User entered 'No (N)'	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-06T17:41:08', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a0a0638f-ab73-4a30-91a3-edfd936d7eee' User entered '06 Sep 2020 17:41'	System	06 Sep 2020 21:41:12
	System	06 Sep 2020 21:41:12

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 7'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'None (0)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:05', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'None (0)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'None (0)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:09', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'None (0)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'None (0)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:14', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'None (0)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:24', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered 'No (N)'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-07T19:12:40', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8adae981-82b9-4aa2-a138-7c964d488dd3'	System	07 Sep 2020 23:12:46
User entered '07 Sep 2020 19:12'	System	07 Sep 2020 23:12:46

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:53:48

US3352297

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:50:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:32:23

US3352297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:50:27
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:32:23

US3352297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:50:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 18:32:23

US3352297

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:50:27
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:32:23

US3352297

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:56:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:32:33

US3352297

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:05
User entered '1'	System	08 Sep 2020 18:32:33

US3352297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:56:47
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 18:08:07

US3352297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:56:47
User entered '15 Sep 2020'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 18:08:07

US3352297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:56:47
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 18:08:07

US3352297

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:56:47
User entered empty.	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 18:08:07

US3352297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:56:54
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	15 Sep 2020 18:08:12

US3352297

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User entered '1'	System	15 Sep 2020 18:08:12

US3352297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:33:58

US3352297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:06
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 16:33:58

US3352297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 16:33:58

US3352297

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:06
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:33:58

US3352297

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:34:03

US3352297

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:23
User entered '1'	System	23 Sep 2020 16:34:03

US3352297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:51:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:22:04

US3352297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:51:42
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:22:04

US3352297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:51:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 15:22:04

US3352297

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'VISIT2'	System	29 Sep 2020 15:22:04

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '08:56'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered '29 Sep 2020 08:56'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '36.9' C	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '54'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'bpm'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '14'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'breaths/min'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '132'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'mmHg'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '74'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'mmHg'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '10:08'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered '29 Sep 2020 10:08'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '36.8' C	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '49'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'bpm'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '12'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'breaths/min'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '122'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'mmHg'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:10
User entered '76'	(b) (4), (b) (6)	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'mmHg'	System	29 Sep 2020 15:23:02

US3352297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:21
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 15:23:08

US3352297

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:21
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:23:08

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered empty.	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered '29 Sep 2020'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered '09:38'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered '29 Sep 2020 09:38'	System	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered 'Left Arm (LEFT ARM)'	Sara Gomez (b) (4) (b) (4)	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:52:33
User entered 'ONCE'	System	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 13:47:43

US3352297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:23:25

US3352297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:17
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:23:25

US3352297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:17
User entered '09:13'	(b) (4), (b) (6)	29 Sep 2020 15:23:25

US3352297

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered '29 Sep 2020 09:13'	System	29 Sep 2020 15:23:25

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:24
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:24
User entered '09:05'	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered '29 Sep 2020 09:05'	System	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:24
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:24
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered empty.	System	29 Sep 2020 15:23:41

US3352297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:53:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:23:47

US3352297

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:03:20
User entered '1'	System	29 Sep 2020 15:23:47

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:10:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '558920f3-81d8-42c9-afdf-5b8cc08a73cd'	System	29 Sep 2020 14:11:14
User entered 'Yes (Y)'	System	29 Sep 2020 14:11:14

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:10:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '558920f3-81d8-42c9-afdf-5b8cc08a73cd' User entered '98.2'	System	29 Sep 2020 14:11:14
	System	29 Sep 2020 14:11:14

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:10:59', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '558920f3-81d8-42c9-afdf-5b8cc08a73cd'	System	29 Sep 2020 14:11:14
User entered 'No (N)'	System	29 Sep 2020 14:11:14

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:05', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '558920f3-81d8-42c9-afdf-5b8cc08a73cd'	System	29 Sep 2020 14:11:14
User entered '29 Sep 2020 10:11'	System	29 Sep 2020 14:11:14

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 09:58'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 12:28'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:42:39', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a406e69a-f2e9-4e63-9beb-0ffc10db0ce'	System	30 Sep 2020 01:42:59
User entered 'Yes (Y)'	System	30 Sep 2020 01:42:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:42:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a406e69a-f2e9-4e63-9beb-0ffc10db0ce'	System	30 Sep 2020 01:42:59
User entered '97.4'	System	30 Sep 2020 01:42:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:42:51', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a406e69a-f2e9-4e63-9beb-0ffcb10db0ce'	System	30 Sep 2020 01:42:59
User entered 'No (N)'	System	30 Sep 2020 01:42:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:42:57', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a406e69a-f2e9-4e63-9beb-0ffcb10db0ce'	System	30 Sep 2020 01:42:59
User entered '29 Sep 2020 21:42'	System	30 Sep 2020 01:42:59

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 13:23'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 2'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '2e97f9b7-e6d4-464d-ace2-4ad62f5a8e24'	System	01 Oct 2020 07:13:34
User entered 'Yes (Y)'	System	01 Oct 2020 07:13:34

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '2e97f9b7-e6d4-464d-ace2-4ad62f5a8e24'	System	01 Oct 2020 07:13:34
User entered '97.4'	System	01 Oct 2020 07:13:34

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:24', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '2e97f9b7-e6d4-464d-ace2-4ad62f5a8e24'	System	01 Oct 2020 07:13:34
User entered 'No (N)'	System	01 Oct 2020 07:13:34

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '2e97f9b7-e6d4-464d-ace2-4ad62f5a8e24'	System	01 Oct 2020 07:13:34
User entered '01 Oct 2020 03:13'	System	01 Oct 2020 07:13:34

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 3'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:01:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a638020e-6fb0-40bb-a612-10a2aa453a99'	System	02 Oct 2020 04:01:55
User entered 'Yes (Y)'	System	02 Oct 2020 04:01:55

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:01:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a638020e-6fb0-40bb-a612-10a2aa453a99'	System	02 Oct 2020 04:01:55
User entered '97.6'	System	02 Oct 2020 04:01:55

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:01:48', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a638020e-6fb0-40bb-a612-10a2aa453a99'	System	02 Oct 2020 04:01:55
User entered 'No (N)'	System	02 Oct 2020 04:01:55

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:01:52', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a638020e-6fb0-40bb-a612-10a2aa453a99'	System	02 Oct 2020 04:01:55
User entered '02 Oct 2020 00:01'	System	02 Oct 2020 04:01:55

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 4'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:04:58', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '671245f6-d816-4e17-a57e-a292e64cc787'	System	02 Oct 2020 22:05:22
User entered 'Yes (Y)'	System	02 Oct 2020 22:05:22

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:09', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '671245f6-d816-4e17-a57e-a292e64cc787'	System	02 Oct 2020 22:05:22
User entered '98.0'	System	02 Oct 2020 22:05:22

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '671245f6-d816-4e17-a57e-a292e64cc787'	System	02 Oct 2020 22:05:22
User entered 'No (N)'	System	02 Oct 2020 22:05:22

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:17', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '671245f6-d816-4e17-a57e-a292e64cc787'	System	02 Oct 2020 22:05:22
User entered '02 Oct 2020 18:05'	System	02 Oct 2020 22:05:22

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 5'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:02:53', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '0a25d730-8c4a-4dc0-9ae9-f439045bd800'	System	03 Oct 2020 22:03:17
User entered 'Yes (Y)'	System	03 Oct 2020 22:03:17

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '0a25d730-8c4a-4dc0-9ae9-f439045bd800'	System	03 Oct 2020 22:03:17
User entered '98.3'	System	03 Oct 2020 22:03:17

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:08', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '0a25d730-8c4a-4dc0-9ae9-f439045bd800'	System	03 Oct 2020 22:03:17
User entered 'No (N)'	System	03 Oct 2020 22:03:17

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:11', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '0a25d730-8c4a-4dc0-9ae9-f439045bd800'	System	03 Oct 2020 22:03:17
User entered '03 Oct 2020 18:03'	System	03 Oct 2020 22:03:17

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 6'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:20', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8e8b9e3-e6d8-4500-9449-f624a30c9e52'	System	04 Oct 2020 23:02:44
User entered 'Yes (Y)'	System	04 Oct 2020 23:02:44

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8e8b9e3-e6d8-4500-9449-f624a30c9e52'	System	04 Oct 2020 23:02:44
User entered '98.7'	System	04 Oct 2020 23:02:44

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8e8b9e3-e6d8-4500-9449-f624a30c9e52'	System	04 Oct 2020 23:02:44
User entered 'No (N)'	System	04 Oct 2020 23:02:44

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8e8b9e3-e6d8-4500-9449-f624a30c9e52'	System	04 Oct 2020 23:02:44
User entered '04 Oct 2020 19:02'	System	04 Oct 2020 23:02:44

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 7'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:20', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5597520f-e4a6-4400-888d-2af46f0c238a'	System	05 Oct 2020 20:46:41
User entered 'Yes (Y)'	System	05 Oct 2020 20:46:41

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5597520f-e4a6-4400-888d-2af46f0c238a'	System	05 Oct 2020 20:46:41
User entered '99.1'	System	05 Oct 2020 20:46:41

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:31', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5597520f-e4a6-4400-888d-2af46f0c238a'	System	05 Oct 2020 20:46:41
User entered 'No (N)'	System	05 Oct 2020 20:46:41

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '5597520f-e4a6-4400-888d-2af46f0c238a'	System	05 Oct 2020 20:46:41
User entered '05 Oct 2020 16:46'	System	05 Oct 2020 20:46:41

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:17', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '246fb726-025a-4ec0-b7d2-9c4f2a5f9be8'	System	29 Sep 2020 14:11:48
User entered 'None (1)'	System	29 Sep 2020 14:11:48

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '246fb726-025a-4ec0-b7d2-9c4f2a5f9be8'	System	29 Sep 2020 14:11:48
User entered 'No (N)'	System	29 Sep 2020 14:11:48

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:34', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '246fb726-025a-4ec0-b7d2-9c4f2a5f9be8'	System	29 Sep 2020 14:11:48
User entered 'No (N)'	System	29 Sep 2020 14:11:48

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '246fb726-025a-4ec0-b7d2-9c4f2a5f9be8'	System	29 Sep 2020 14:11:48
User entered 'None (1)'	System	29 Sep 2020 14:11:48

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:45', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '246fb726-025a-4ec0-b7d2-9c4f2a5f9be8' User entered '29 Sep 2020 10:11'	System	29 Sep 2020 14:11:48
	System	29 Sep 2020 14:11:48

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 09:58'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 12:28'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:15', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bcfa3aa3-4643-459b-8cb7-d6ad2fea06e0'	System	30 Sep 2020 01:43:41
User entered 'None (1)'	System	30 Sep 2020 01:43:41

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:18', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bcfa3aa3-4643-459b-8cb7-d6ad2fea06e0'	System	30 Sep 2020 01:43:41
User entered 'No (N)'	System	30 Sep 2020 01:43:41

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:22', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bcfa3aa3-4643-459b-8cb7-d6ad2fea06e0'	System	30 Sep 2020 01:43:41
User entered 'No (N)'	System	30 Sep 2020 01:43:41

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bcfa3aa3-4643-459b-8cb7-d6ad2fea06e0'	System	30 Sep 2020 01:43:41
User entered 'None (1)'	System	30 Sep 2020 01:43:41

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:39', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bcfa3aa3-4643-459b-8cb7-d6ad2fea06e0'	System	30 Sep 2020 01:43:41
User entered '29 Sep 2020 21:43'	System	30 Sep 2020 01:43:41

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 13:23'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 2'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe44592a-99e7-4144-92de-14c3652d316b'	System	01 Oct 2020 07:14:04
User entered 'None (1)'	System	01 Oct 2020 07:14:04

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe44592a-99e7-4144-92de-14c3652d316b'	System	01 Oct 2020 07:14:04
User entered 'No (N)'	System	01 Oct 2020 07:14:04

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe44592a-99e7-4144-92de-14c3652d316b'	System	01 Oct 2020 07:14:04
User entered 'No (N)'	System	01 Oct 2020 07:14:04

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:13:56', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe44592a-99e7-4144-92de-14c3652d316b'	System	01 Oct 2020 07:14:04
User entered 'None (1)'	System	01 Oct 2020 07:14:04

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe44592a-99e7-4144-92de-14c3652d316b'	System	01 Oct 2020 07:14:04
User entered '01 Oct 2020 03:14'	System	01 Oct 2020 07:14:04

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 3'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:01', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e5dfb291-6d81-4854-a4a9-220005a14afc'	System	02 Oct 2020 04:02:31
User entered 'None (1)'	System	02 Oct 2020 04:02:31

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:05', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e5dfb291-6d81-4854-a4a9-220005a14afc'	System	02 Oct 2020 04:02:31
User entered 'No (N)'	System	02 Oct 2020 04:02:31

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:08', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e5dfb291-6d81-4854-a4a9-220005a14afc'	System	02 Oct 2020 04:02:31
User entered 'No (N)'	System	02 Oct 2020 04:02:31

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:17', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e5dfb291-6d81-4854-a4a9-220005a14afc'	System	02 Oct 2020 04:02:31
User entered 'None (1)'	System	02 Oct 2020 04:02:31

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:26', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e5dfb291-6d81-4854-a4a9-220005a14afc'	System	02 Oct 2020 04:02:31
User entered '02 Oct 2020 00:02'	System	02 Oct 2020 04:02:31

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 4'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:31', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e35aa49d-3628-4ae0-ac98-539b0623186b'	System	02 Oct 2020 22:06:06
User entered 'None (1)'	System	02 Oct 2020 22:06:06

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:35', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e35aa49d-3628-4ae0-ac98-539b0623186b'	System	02 Oct 2020 22:06:06
User entered 'No (N)'	System	02 Oct 2020 22:06:06

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e35aa49d-3628-4ae0-ac98-539b0623186b'	System	02 Oct 2020 22:06:06
User entered 'No (N)'	System	02 Oct 2020 22:06:06

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:05:56', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e35aa49d-3628-4ae0-ac98-539b0623186b'	System	02 Oct 2020 22:06:06
User entered 'None (1)'	System	02 Oct 2020 22:06:06

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:01', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'e35aa49d-3628-4ae0-ac98-539b0623186b' User entered '02 Oct 2020 18:06'	System	02 Oct 2020 22:06:06
	System	02 Oct 2020 22:06:06

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 5'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:17', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd70f1d23-9694-4f79-99ec-34c83e01bf00'	System	03 Oct 2020 22:03:44
User entered 'None (1)'	System	03 Oct 2020 22:03:44

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:21', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd70f1d23-9694-4f79-99ec-34c83e01bf00'	System	03 Oct 2020 22:03:44
User entered 'No (N)'	System	03 Oct 2020 22:03:44

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:26', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd70f1d23-9694-4f79-99ec-34c83e01bf00'	System	03 Oct 2020 22:03:44
User entered 'No (N)'	System	03 Oct 2020 22:03:44

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:32', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd70f1d23-9694-4f79-99ec-34c83e01bf00'	System	03 Oct 2020 22:03:44
User entered 'None (1)'	System	03 Oct 2020 22:03:44

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:39', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd70f1d23-9694-4f79-99ec-34c83e01bf00'	System	03 Oct 2020 22:03:44
User entered '03 Oct 2020 18:03'	System	03 Oct 2020 22:03:44

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 6'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8643122-9bbe-4f20-9c75-a3b2c9e346b0'	System	04 Oct 2020 23:03:27
User entered 'None (1)'	System	04 Oct 2020 23:03:27

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:53', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8643122-9bbe-4f20-9c75-a3b2c9e346b0'	System	04 Oct 2020 23:03:27
User entered 'No (N)'	System	04 Oct 2020 23:03:27

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:02:57', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8643122-9bbe-4f20-9c75-a3b2c9e346b0'	System	04 Oct 2020 23:03:27
User entered 'No (N)'	System	04 Oct 2020 23:03:27

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:13', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8643122-9bbe-4f20-9c75-a3b2c9e346b0'	System	04 Oct 2020 23:03:27
User entered 'None (1)'	System	04 Oct 2020 23:03:27

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c8643122-9bbe-4f20-9c75-a3b2c9e346b0'	System	04 Oct 2020 23:03:27
User entered '04 Oct 2020 19:03'	System	04 Oct 2020 23:03:27

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 7'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:45', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6971cf87-a105-4310-aded-482a44cc8143'	System	05 Oct 2020 20:47:09
User entered 'None (1)'	System	05 Oct 2020 20:47:09

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:49', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6971cf87-a105-4310-aded-482a44cc8143'	System	05 Oct 2020 20:47:09
User entered 'No (N)'	System	05 Oct 2020 20:47:09

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:55', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6971cf87-a105-4310-aded-482a44cc8143'	System	05 Oct 2020 20:47:09
User entered 'No (N)'	System	05 Oct 2020 20:47:09

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:46:59', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6971cf87-a105-4310-aded-482a44cc8143'	System	05 Oct 2020 20:47:09
User entered 'None (1)'	System	05 Oct 2020 20:47:09

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6971cf87-a105-4310-aded-482a44cc8143'	System	05 Oct 2020 20:47:09
User entered '05 Oct 2020 16:47'	System	05 Oct 2020 20:47:09

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:50', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'None (0)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:52', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'None (0)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:55', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'None (0)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:11:58', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'None (0)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:12:01', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'None (0)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:12:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'None (0)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:12:25', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered 'No (N)'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T10:12:30', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1e3358b4-bf37-46a8-82c1-a50765d5fae9'	System	29 Sep 2020 14:12:37
User entered '29 Sep 2020 10:12'	System	29 Sep 2020 14:12:37

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 09:58'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 12:28'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:47', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'None (0)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:43:55', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'None (0)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:44:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'None (0)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:44:06', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'None (0)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:44:10', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'None (0)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:44:21', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'None (0)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:44:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered 'No (N)'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-09-29T21:44:31', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49c17477-ac5f-4ae1-b81d-4800c9c40280'	System	30 Sep 2020 01:44:34
User entered '29 Sep 2020 21:44'	System	30 Sep 2020 01:44:34

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '29 Sep 2020 13:23'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 2'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'None (0)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:18', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'None (0)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:21', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'None (0)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:24', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'None (0)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:28', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'None (0)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:31', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'None (0)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered 'No (N)'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-01T03:14:40', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ebfbd4ef-9ab9-4962-8f56-856eecd83e0d'	System	01 Oct 2020 07:14:46
User entered '01 Oct 2020 03:14'	System	01 Oct 2020 07:14:46

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 3'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'None (0)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'None (0)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'None (0)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:44', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'None (0)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:02:58', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'None (0)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:03:01', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'None (0)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:03:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered 'No (N)'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T00:03:09', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9643c67b-48c5-4fb4-a36a-e520be780b4d'	System	02 Oct 2020 04:03:13
User entered '02 Oct 2020 00:03'	System	02 Oct 2020 04:03:13

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 4'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:11', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'None (0)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:17', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'None (0)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:21', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'None (0)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:25', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'None (0)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:29', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'None (0)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'None (0)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:46', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered 'No (N)'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-02T18:06:49', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '72e45861-cf4f-41f9-b2ba-e165f1a447ad'	System	02 Oct 2020 22:06:56
User entered '02 Oct 2020 18:06'	System	02 Oct 2020 22:06:56

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 5'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:03:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'None (0)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:04:22', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'None (0)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:04:25', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'None (0)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:04:36', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'None (0)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:06:16', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'None (0)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:06:18', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'None (0)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:06:23', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered 'No (N)'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-03T18:06:26', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '8d20b75b-9634-4cca-b722-4de9cb54b721'	System	03 Oct 2020 22:06:31
User entered '03 Oct 2020 18:06'	System	03 Oct 2020 22:06:31

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 6'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'None (0)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:32', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'None (0)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:40', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'None (0)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:45', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'None (0)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:03:59', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'None (0)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:04:08', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'None (0)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:04:15', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419'	System	04 Oct 2020 23:04:52
User entered 'No (N)'	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-04T19:04:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'acd0d033-67b0-4cc4-82dd-e1b9a15de419' User entered '04 Oct 2020 19:04'	System	04 Oct 2020 23:04:52
	System	04 Oct 2020 23:04:52

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	29 Sep 2020 13:47:43
User entered 'Day 7'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:13', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'None (0)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:16', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'None (0)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'None (0)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:24', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'None (0)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:32', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'None (0)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:34', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'None (0)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered 'No (N)'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-10-05T16:47:44', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '203de7d9-32c1-4432-aa5b-aaa58ee1998f'	System	05 Oct 2020 20:47:49
User entered '05 Oct 2020 16:47'	System	05 Oct 2020 20:47:49

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:47:43

US3352297

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:47:43

US3352297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:47
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:31:59

US3352297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:47
User entered '6 Oct 2020'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:31:59

US3352297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:47
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:31:59

US3352297

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:47
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:31:59

US3352297

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:54
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	06 Oct 2020 13:32:04

US3352297

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:17:41
User entered '1'	System	06 Oct 2020 13:32:04

US3352297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:03:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:45:09

US3352297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:03:35
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 20:45:09

US3352297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:03:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 20:45:09

US3352297

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:03:35
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 20:45:09

US3352297

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:45
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:45:14

US3352297

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:45
User entered 'I'	System	14 Oct 2020 20:45:14

US3352297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:12:57

US3352297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:12
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:12:57

US3352297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 19:12:57

US3352297

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:12
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:12:57

US3352297

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:09:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:13:00

US3352297

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:46
User entered '1'	System	20 Oct 2020 19:13:00

US3352297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:12:56

US3352297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:08
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:12:56

US3352297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 14:12:56

US3352297

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered 'VISIT3'	System	27 Oct 2020 14:12:56

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '08:13'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered '27 Oct 2020 08:13'	System	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '37.0' C	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '65'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered 'bpm'	System	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '14'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered 'breaths/min'	System	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '138'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered 'mmHg'	System	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:46
User entered '80'	(b) (4), (b) (6)	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered 'mmHg'	System	27 Oct 2020 14:13:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12

US3352297

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12

US3352297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:13:53

US3352297

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:54:56
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:13:53

US3352297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:55:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:14:08

US3352297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:55:05
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:14:08

US3352297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:55:05
User entered '08:25'	(b) (4), (b) (6)	27 Oct 2020 14:14:08

US3352297

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered '27 Oct 2020 08:25'	System	27 Oct 2020 14:14:08

US3352297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:55:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:12:47

US3352297

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:25:12
User entered '1'	System	27 Oct 2020 14:12:47

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 64'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-05T11:54:06', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7a07524d-5390-46ae-826a-cfd116db72c6'	System	05 Nov 2020 16:55:07
User entered 'No (N)'	System	05 Nov 2020 16:55:07

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-05T11:54:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7a07524d-5390-46ae-826a-cfd116db72c6'	System	05 Nov 2020 16:55:07
User entered 'Yes (Y)'	System	05 Nov 2020 16:55:07

US3352297

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-05T11:54:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7a07524d-5390-46ae-826a-cfd116db72c6'	System	05 Nov 2020 16:55:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Nov 2020 16:55:07

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-05T11:54:51', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7a07524d-5390-46ae-826a-cfd116db72c6'	System	05 Nov 2020 16:55:07
User entered '05 Nov 2020 11:54:51'	System	05 Nov 2020 16:55:07

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 71'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-08T06:26:52', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ffb6d243-96f4-43de-a2d5-de8f601dd98a'	System	08 Nov 2020 11:27:42
User entered 'No (N)'	System	08 Nov 2020 11:27:42

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-08T06:27:13', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ffb6d243-96f4-43de-a2d5-de8f601dd98a'	System	08 Nov 2020 11:27:42
User entered 'Yes (Y)'	System	08 Nov 2020 11:27:42

US3352297

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-08T06:27:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ffb6d243-96f4-43de-a2d5-de8f601dd98a'	System	08 Nov 2020 11:27:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 11:27:42

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-08T06:27:31', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'ffb6d243-96f4-43de-a2d5-de8f601dd98a' User entered '08 Nov 2020 06:27:31'	System	08 Nov 2020 11:27:42
	System	08 Nov 2020 11:27:42

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered 'Day 78'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-15T07:16:19', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd1a92e3f-3913-445e-9b79-d27314997886'	System	15 Nov 2020 12:16:38
User entered 'No (N)'	System	15 Nov 2020 12:16:38

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-15T07:16:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd1a92e3f-3913-445e-9b79-d27314997886'	System	15 Nov 2020 12:16:38
User entered 'No (N)'	System	15 Nov 2020 12:16:38

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-15T07:16:34', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd1a92e3f-3913-445e-9b79-d27314997886'	System	15 Nov 2020 12:16:38
User entered '15 Nov 2020 07:16:34'	System	15 Nov 2020 12:16:38

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 15:53:48

US3352297

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:27:18
Data entry locked.	System	01 Sep 2020 15:53:48
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 15:53:48

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2020-11-28T13:33:04', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bab0f9f7-0d13-4bab-b589-258c3d1083b9'	System	28 Nov 2020 18:33:27
User entered 'No (N)'	System	28 Nov 2020 18:33:27

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2020-11-28T13:33:10', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bab0f9f7-0d13-4bab-b589-258c3d1083b9'	System	28 Nov 2020 18:33:27
User entered 'No (N)'	System	28 Nov 2020 18:33:27

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-11-28T13:33:20', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'bab0f9f7-0d13-4bab-b589-258c3d1083b9'	System	28 Nov 2020 18:33:27
User entered '28 Nov 2020 13:33:20'	System	28 Nov 2020 18:33:27

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2020-12-10T07:38:58', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '67faa90e-ed13-4f4e-880e-fe8e0f2fdef8'	System	10 Dec 2020 12:39:16
User entered 'No (N)'	System	10 Dec 2020 12:39:16

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2020-12-10T07:39:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '67faa90e-ed13-4f4e-880e-fe8e0f2fdef8'	System	10 Dec 2020 12:39:16
User entered 'No (N)'	System	10 Dec 2020 12:39:16

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-12-10T07:39:12', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '67faa90e-ed13-4f4e-880e-fe8e0f2fdef8'	System	10 Dec 2020 12:39:16
User entered '10 Dec 2020 07:39:12'	System	10 Dec 2020 12:39:16

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2020-12-18T20:56:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9cc1042b-9afd-4ed9-90ae-32a44ecce952'	System	19 Dec 2020 01:56:17
User entered 'No (N)'	System	19 Dec 2020 01:56:17

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2020-12-18T20:56:07', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9cc1042b-9afd-4ed9-90ae-32a44ecce952'	System	19 Dec 2020 01:56:17
User entered 'No (N)'	System	19 Dec 2020 01:56:17

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-12-18T20:56:11', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '9cc1042b-9afd-4ed9-90ae-32a44ecce952'	System	19 Dec 2020 01:56:17
User entered '18 Dec 2020 20:56:11'	System	19 Dec 2020 01:56:17

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2020-12-24T07:01:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c87e2a10-9171-4156-a951-c80804cc83f1'	System	24 Dec 2020 12:01:27
User entered 'No (N)'	System	24 Dec 2020 12:01:27

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2020-12-24T07:01:13', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c87e2a10-9171-4156-a951-c80804cc83f1'	System	24 Dec 2020 12:01:27
User entered 'No (N)'	System	24 Dec 2020 12:01:27

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2020-12-24T07:01:18', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'c87e2a10-9171-4156-a951-c80804cc83f1'	System	24 Dec 2020 12:01:27
User entered '24 Dec 2020 07:01:18'	System	24 Dec 2020 12:01:27

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-01-01T09:34:05', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '83fcdd76-7ecd-47f0-8e76-347b70e32145'	System	01 Jan 2021 14:34:25
User entered 'No (N)'	System	01 Jan 2021 14:34:25

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-01-01T09:34:14', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '83fcdd76-7ecd-47f0-8e76-347b70e32145'	System	01 Jan 2021 14:34:25
User entered 'No (N)'	System	01 Jan 2021 14:34:25

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-01T09:34:20', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '83fcdd76-7ecd-47f0-8e76-347b70e32145'	System	01 Jan 2021 14:34:25
User entered '01 Jan 2021 09:34:20'	System	01 Jan 2021 14:34:25

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-01-11T12:14:24', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '96e2ec73-f832-400e-9032-c02a76c4083a'	System	11 Jan 2021 17:14:45
User entered 'No (N)'	System	11 Jan 2021 17:14:45

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-01-11T12:14:33', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '96e2ec73-f832-400e-9032-c02a76c4083a'	System	11 Jan 2021 17:14:45
User entered 'No (N)'	System	11 Jan 2021 17:14:45

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-11T12:14:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '96e2ec73-f832-400e-9032-c02a76c4083a' User entered '11 Jan 2021 12:14:37'	System	11 Jan 2021 17:14:45
	System	11 Jan 2021 17:14:45

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-01-15T12:13:49', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe0b4582-908d-43f2-b04a-101c2ee09be8'	System	15 Jan 2021 17:14:08
User entered 'No (N)'	System	15 Jan 2021 17:14:08

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-01-15T12:13:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe0b4582-908d-43f2-b04a-101c2ee09be8'	System	15 Jan 2021 17:14:08
User entered 'No (N)'	System	15 Jan 2021 17:14:08

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-15T12:14:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'fe0b4582-908d-43f2-b04a-101c2ee09be8'	System	15 Jan 2021 17:14:08
User entered '15 Jan 2021 12:14:02'	System	15 Jan 2021 17:14:08

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-01-25T14:38:27', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49437f14-c24f-4169-9ecb-e0c0ab84396d'	System	25 Jan 2021 19:39:20
User entered 'Yes (Y)'	System	25 Jan 2021 19:39:20

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-01-25T14:38:38', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49437f14-c24f-4169-9ecb-e0c0ab84396d'	System	25 Jan 2021 19:39:20
User entered 'No (N)'	System	25 Jan 2021 19:39:20

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-25T14:38:44', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49437f14-c24f-4169-9ecb-e0c0ab84396d'	System	25 Jan 2021 19:39:20
User entered 'No (N)'	System	25 Jan 2021 19:39:20

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-25T14:38:53', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49437f14-c24f-4169-9ecb-e0c0ab84396d'	System	25 Jan 2021 19:39:20
User entered 'Yes (Y)'	System	25 Jan 2021 19:39:20

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-25T14:39:02', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49437f14-c24f-4169-9ecb-e0c0ab84396d'	System	25 Jan 2021 19:39:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 19:39:20

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-25T14:39:06', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '49437f14-c24f-4169-9ecb-e0c0ab84396d'	System	25 Jan 2021 19:39:20
User entered '25 Jan 2021 14:39:06'	System	25 Jan 2021 19:39:20

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-01-28T05:18:37', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1de563cd-59ad-469c-9054-715648ce5643'	System	28 Jan 2021 10:18:53
User entered 'No (N)'	System	28 Jan 2021 10:18:53

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-01-28T05:18:41', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1de563cd-59ad-469c-9054-715648ce5643'	System	28 Jan 2021 10:18:53
User entered 'No (N)'	System	28 Jan 2021 10:18:53

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-01-28T05:18:44', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1de563cd-59ad-469c-9054-715648ce5643'	System	28 Jan 2021 10:18:53
User entered '28 Jan 2021 05:18:44'	System	28 Jan 2021 10:18:53

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-02-04T04:34:16', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6099b2b4-44a7-4f3b-81b3-57ff79eaa0a7'	System	04 Feb 2021 09:34:38
User entered 'No (N)'	System	04 Feb 2021 09:34:38

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-02-04T04:34:21', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6099b2b4-44a7-4f3b-81b3-57ff79eaa0a7'	System	04 Feb 2021 09:34:38
User entered 'No (N)'	System	04 Feb 2021 09:34:38

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-02-04T04:34:32', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6099b2b4-44a7-4f3b-81b3-57ff79eaa0a7'	System	04 Feb 2021 09:34:38
User entered '04 Feb 2021 04:34:32'	System	04 Feb 2021 09:34:38

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-02-12T08:39:14', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd5571805-df25-435d-a11c-31f95c899913'	System	12 Feb 2021 13:39:29
User entered 'No (N)'	System	12 Feb 2021 13:39:29

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-02-12T08:39:21', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd5571805-df25-435d-a11c-31f95c899913'	System	12 Feb 2021 13:39:29
User entered 'No (N)'	System	12 Feb 2021 13:39:29

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-02-12T08:39:24', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'd5571805-df25-435d-a11c-31f95c899913'	System	12 Feb 2021 13:39:29
User entered '12 Feb 2021 08:39:24'	System	12 Feb 2021 13:39:29

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-02-19T11:23:48', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7fbf24f9-dbbb-4e49-90aa-49d9f4b55805'	System	19 Feb 2021 16:24:09
User entered 'No (N)'	System	19 Feb 2021 16:24:09

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-02-19T11:23:54', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7fbf24f9-dbbb-4e49-90aa-49d9f4b55805'	System	19 Feb 2021 16:24:09
User entered 'No (N)'	System	19 Feb 2021 16:24:09

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-02-19T11:24:01', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '7fbf24f9-dbbb-4e49-90aa-49d9f4b55805'	System	19 Feb 2021 16:24:09
User entered '19 Feb 2021 11:24:01'	System	19 Feb 2021 16:24:09

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-03-01T14:12:51-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '83584e8f-d1fe-45ff-89bb-43aaa182f8ac'	System	01 Mar 2021 19:13:07
User entered 'No (N)'	System	01 Mar 2021 19:13:07

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-03-01T14:12:54-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '83584e8f-d1fe-45ff-89bb-43aaa182f8ac'	System	01 Mar 2021 19:13:07
User entered 'No (N)'	System	01 Mar 2021 19:13:07

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-03-01T14:12:57-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '83584e8f-d1fe-45ff-89bb-43aaa182f8ac' User entered '01 Mar 2021 14:12:57'	System	01 Mar 2021 19:13:07
	System	01 Mar 2021 19:13:07

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-03-04T02:17:33-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6a99d716-7324-40d1-b3ea-d508ef8bb088'	System	04 Mar 2021 07:17:58
User entered 'No (N)'	System	04 Mar 2021 07:17:58

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-03-04T02:17:38-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6a99d716-7324-40d1-b3ea-d508ef8bb088'	System	04 Mar 2021 07:17:58
User entered 'No (N)'	System	04 Mar 2021 07:17:58

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-03-04T02:17:43-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '6a99d716-7324-40d1-b3ea-d508ef8bb088' User entered '04 Mar 2021 02:17:43'	System	04 Mar 2021 07:17:58
	System	04 Mar 2021 07:17:58

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-03-12T09:29:36-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b709b6a9-1699-4b17-b153-dce3a2be660e'	System	12 Mar 2021 14:29:53
User entered 'No (N)'	System	12 Mar 2021 14:29:53

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-03-12T09:29:44-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b709b6a9-1699-4b17-b153-dce3a2be660e'	System	12 Mar 2021 14:29:53
User entered 'No (N)'	System	12 Mar 2021 14:29:53

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-03-12T09:29:48-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'b709b6a9-1699-4b17-b153-dce3a2be660e' User entered '12 Mar 2021 09:29:48'	System	12 Mar 2021 14:29:53
	System	12 Mar 2021 14:29:53

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-03-20T15:34:17-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a04da2ef-9204-4c2e-b9c2-031d0e603891' User entered 'No (N)'	System	20 Mar 2021 19:34:34
	System	20 Mar 2021 19:34:34

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-03-20T15:34:22-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a04da2ef-9204-4c2e-b9c2-031d0e603891'	System	20 Mar 2021 19:34:34
User entered 'No (N)'	System	20 Mar 2021 19:34:34

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-03-20T15:34:26-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: 'a04da2ef-9204-4c2e-b9c2-031d0e603891' User entered '20 Mar 2021 15:34:26'	System	20 Mar 2021 19:34:34
	System	20 Mar 2021 19:34:34

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-04-03T00:08:54-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '4ea2b6ec-5520-4566-8308-27f4c2a96341'	System	03 Apr 2021 04:09:10
User entered 'No (N)'	System	03 Apr 2021 04:09:10

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-04-03T00:08:59-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '4ea2b6ec-5520-4566-8308-27f4c2a96341'	System	03 Apr 2021 04:09:10
User entered 'No (N)'	System	03 Apr 2021 04:09:10

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-04-03T00:09:02-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '4ea2b6ec-5520-4566-8308-27f4c2a96341'	System	03 Apr 2021 04:09:10
User entered '03 Apr 2021 00:09:02'	System	03 Apr 2021 04:09:10

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-04-11T05:29:35-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3a5fc2e1-e639-4394-9e3b-9e16f6f2313e'	System	11 Apr 2021 09:29:48
User entered 'No (N)'	System	11 Apr 2021 09:29:48

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-04-11T05:29:39-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3a5fc2e1-e639-4394-9e3b-9e16f6f2313e'	System	11 Apr 2021 09:29:48
User entered 'No (N)'	System	11 Apr 2021 09:29:48

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-04-11T05:29:43-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '3a5fc2e1-e639-4394-9e3b-9e16f6f2313e' User entered '11 Apr 2021 05:29:43'	System	11 Apr 2021 09:29:48
	System	11 Apr 2021 09:29:48

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[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 (f730afd2c06874af)', Time: '2021-05-01T05:58:49-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '910bfe44-acc4-4100-aff2-a757f0b4db43'	System	01 May 2021 09:59:08
User entered 'No (N)'	System	01 May 2021 09:59:08

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

Have you been exposed to someone with 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 (f730afd2c06874af)', Time: '2021-05-01T05:58:54-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '910bfe44-acc4-4100-aff2-a757f0b4db43'	System	01 May 2021 09:59:08
User entered 'No (N)'	System	01 May 2021 09:59:08

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-05-01T05:58:57-04:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '910bfe44-acc4-4100-aff2-a757f0b4db43'	System	01 May 2021 09:59:08
User entered '01 May 2021 05:58:57'	System	01 May 2021 09:59:08

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:34:01

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:12:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:34:01

US3352297

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:01
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:34:01

US3352297

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:12:18**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:38:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-03-01T14:12:36-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1c2c07c3-ece1-44b2-a62c-ba8c1bbd4705'	System	01 Mar 2021 19:12:50
User entered 'No (N)'	System	01 Mar 2021 19:12:50

US3352297

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:12:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:38:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f730afd2c06874af)', Time: '2021-03-01T14:12:41-05:00', User OID: 'PatientReportedOutcome (US3352297)', ODM File OID: '1c2c07c3-ece1-44b2-a62c-ba8c1bbd4705'	System	01 Mar 2021 19:12:50
User entered '01 Mar 2021 14:12:41'	System	01 Mar 2021 19:12:50

US3352297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	23 Nov 2020 15:49:15

US3352297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:06
User entered '23 Nov 2020'	Yulexis Amestoy (b) (4)	23 Nov 2020 15:49:15

US3352297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:06
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	23 Nov 2020 15:49:15

US3352297

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:06
User entered empty.	Yulexis Amestoy (b) (4)	23 Nov 2020 15:49:15

US3352297

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:10
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:11:13
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	23 Nov 2020 15:49:20

US3352297

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:40:10
User entered '1'	System	23 Nov 2020 15:49:20

US3352297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:42
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	30 Dec 2020 16:13:17

US3352297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:42
User entered '30 Dec 2020'	Sara Gomez (b) (4) (b) (4)	30 Dec 2020 16:13:17

US3352297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:42
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4) (b) (4)	30 Dec 2020 16:13:17

US3352297

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:42
User entered empty.	Sara Gomez (b) (4) (b) (4)	30 Dec 2020 16:13:17

US3352297

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:12:55
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	30 Dec 2020 16:18:25

US3352297

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User entered 'I'	System	30 Dec 2020 16:18:25

US3352297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:22
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 16:38:50

US3352297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:22
User entered '26 Jan 2021'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 16:38:50

US3352297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:22
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 16:38:50

US3352297

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:22
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 16:38:50

US3352297

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:50:13
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 16:38:55

US3352297

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User entered '1'	System	26 Jan 2021 16:38:55

US3352297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:25:34

US3352297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:44
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:25:34

US3352297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 18:25:34

US3352297

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:44
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:25:34

US3352297

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:13:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:25:27

US3352297

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:36:44
User entered '1'	System	23 Feb 2021 18:25:27

US3352297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:39:19
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	18 Mar 2021 14:22:37

US3352297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:39:19
User entered '16 Mar 2021'	Yulexis Amestoy (b) (4) (b) (4)	18 Mar 2021 14:22:37

US3352297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:39:19
User entered 'Clinic (Clinic)'	Yulexis Amestoy (b) (4) (b) (4)	18 Mar 2021 14:22:37

US3352297

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered 'VISIT4'	System	18 Mar 2021 14:22:37

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '16 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '11:00'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered '16 Mar 2021 11:00'	System	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '37.0' C	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '55'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered 'bpm'	System	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '12'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered 'breaths/min'	System	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '122'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered 'mmHg'	System	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:03
User entered '72'	(b) (4), (b) (6)	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered 'mmHg'	System	31 Mar 2021 15:34:44

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24

US3352297

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24

US3352297

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 17:17:01
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	23 Mar 2021 18:06:08

US3352297

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 17:17:01
User entered '16 Mar 2021'	Yulexis Amestoy (b) (4) (b) (4)	23 Mar 2021 18:06:08

US3352297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:26
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	23 Mar 2021 18:06:32

US3352297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:26
User entered '16 Mar 2021'	Yulexis Amestoy (b) (4) (b) (4)	23 Mar 2021 18:06:32

US3352297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:40:26
User entered '11:07'	Yulexis Amestoy (b) (4) (b) (4)	23 Mar 2021 18:06:32

US3352297

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered '16 Mar 2021 11:07'	System	23 Mar 2021 18:06:32

US3352297

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:41:37
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	23 Mar 2021 18:05:55

US3352297

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:24
User entered '1'	System	23 Mar 2021 18:05:55

US3352297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 15:08:07

US3352297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered '26 Apr 2021'	(b) (4), (b) (6)	26 Apr 2021 15:08:07

US3352297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Apr 2021 15:08:07

US3352297

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 15:08:07

US3352297

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 15:08:00

US3352297

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 15:08:00

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US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:05:45

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:32
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 21:05:45

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Jan 2021 21:05:45

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 21:05:45

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
User closed query 'Please enter vital signs. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:25:01
Query 'Please enter vital signs. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	17 Mar 2021 19:41:57
User opened query 'Please enter vital signs. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:04:32
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:42:36
User entered '0'	Matthew Muniz (b) (4)	10 Mar 2021 19:13:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:21

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:42:41
User entered 'Amendment 6 or later (Amendment 6 or later)'	Matthew Muniz (b) (4)	10 Mar 2021 19:13:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:21

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:36:08
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:36:08
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:03:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '1'	System	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:12:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '1'	System	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered missing code ND - Not Done.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered missing code ND - Not Done.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered empty.	System	17 Mar 2021 19:41:40
DataPoint set to visible.	System	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered missing code ND - Not Done.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered missing code ND - Not Done.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered empty.	System	17 Mar 2021 19:41:40
DataPoint set to visible.	System	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '16 Jan 2021'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '14:08'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '16 Jan 2021 14:08'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '37.6' C	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered empty.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

(

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '60'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'bpm'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '15'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'breaths/min'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '147'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'mmHg'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '78'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'mmHg'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered missing code ND - Not Done.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered missing code ND - Not Done.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:12:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered empty.	System	17 Mar 2021 19:41:40
DataPoint set to visible.	System	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:41:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 19:41:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	17 Mar 2021 19:41:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:41:40
User entered empty.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '16 Jan 2021'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '15:14'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '16 Jan 2021 15:14'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '36.8' C	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered empty.	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '52'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'bpm'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '13'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'breaths/min'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '125'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'mmHg'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:56
User entered '75'	Matthew Muniz (b) (4)	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'mmHg'	System	17 Mar 2021 19:41:40

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:55
User entered 'No (N)'	(b) (4), (b) (6)	16 Jan 2021 21:08:08

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:55
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 21:08:08

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'mRNA-1273'	System	16 Jan 2021 21:13:07
DataPoint set to visible.	System	16 Jan 2021 21:07:52

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	16 Jan 2021 21:14:12
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Jan 2021 21:14:12
User closed query 'Start Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	16 Jan 2021 21:14:12
User closed query 'Start Date is prior to the Date of Randomization. Please review and provide any needed correction.' (Site from System).	System	16 Jan 2021 21:14:12
User entered '16 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Jan 2021 21:14:12
User opened query 'Start Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	16 Jan 2021 21:13:07
User opened query 'Start Date is prior to the Date of Randomization. Please review and provide any needed correction.' (Site from System).	System	16 Jan 2021 21:13:07
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	16 Jan 2021 21:13:07
User entered '16 Jan 2016'	(b) (4), (b) (6)	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User entered '14:44'	(b) (4), (b) (6)	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '16 Jan 2021 14:44'	System	16 Jan 2021 21:14:12
User entered '16 Jan 2016 14:44'	System	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:13
User entered 'ONCE'	System	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered 'INTRAMUSCULAR'	System	16 Jan 2021 21:13:07

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:14:35

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:31
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 21:14:35

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:31
User entered '14:20'	(b) (4), (b) (6)	16 Jan 2021 21:14:35

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '16 Jan 2021 14:20'	System	16 Jan 2021 21:14:35

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:15:15

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:37
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 21:15:15

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:37
User entered '14:13'	(b) (4), (b) (6)	16 Jan 2021 21:15:15

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:12:18

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '16 Jan 2021 14:13'	System	16 Jan 2021 21:15:15

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 21:15:33

US3352297

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:12
User entered '1'	System	16 Jan 2021 21:15:33

US3352297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:57:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Jan 2021 14:38:03

US3352297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:57:52
User entered '23 Jan 2021'	(b) (4), (b) (6)	23 Jan 2021 14:38:03

US3352297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:57:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Jan 2021 14:38:03

US3352297

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:57:52
User entered empty.	(b) (4), (b) (6)	23 Jan 2021 14:38:03

US3352297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:57:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Jan 2021 14:38:08

US3352297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User entered '1'	System	23 Jan 2021 14:38:08

US3352297

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:24
User entered '1'	System	23 Jan 2021 14:38:08
DataPoint set to visible.	System	23 Jan 2021 14:38:08

US3352297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:02:34
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 20:11:43

US3352297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:02:34
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 20:11:43

US3352297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:02:34
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	15 Feb 2021 20:11:43

US3352297

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'OLD29'	System	15 Feb 2021 20:11:43

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User accepted default value 'Pre-Dose (PREDOSE)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '08:25'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered '13 Feb 2021 08:25'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '37.0' C	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered empty.	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '56'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'bpm'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '15'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'breaths/min'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '140'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'mmHg'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '77'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'mmHg'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User accepted default value 'Post-Dose (POSTDOSE)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '09:51'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered '13 Feb 2021 09:51'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '36.5' C	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered empty.	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '56'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'bpm'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '14'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'breaths/min'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '138'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'mmHg'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:12
User entered '80'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'mmHg'	System	15 Feb 2021 20:13:11

US3352297

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:22
User entered 'No (N)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:17

US3352297

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:22
User entered empty.	Wanda Delgado (b) (4)	15 Feb 2021 20:13:17

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered empty.	Wanda Delgado (b) (4)	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered empty.	Wanda Delgado (b) (4)	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'mRNA-1273'	System	15 Feb 2021 20:13:36
DataPoint set to visible.	System	23 Jan 2021 14:38:08

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered '13 Feb 2021'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered '09:20'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered '13 Feb 2021 09:20'	System	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered 'Left Arm (LEFT ARM)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered 'ONCE'	System	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:12:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 20:13:36

US3352297

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:08:17
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	15 Feb 2021 20:13:41

US3352297

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:47
User entered '1'	System	15 Feb 2021 20:13:41

US3352297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 21:54:26

US3352297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:52
User entered '20 Feb 2021'	(b) (4), (b) (6)	20 Feb 2021 21:54:26

US3352297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Feb 2021 21:54:26

US3352297

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:12:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:52
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 21:54:26

US3352297

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Feb 2021 21:54:30

US3352297

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:34:27
User entered '1'	System	20 Feb 2021 21:54:30

US3352297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:09:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 20:42:44

US3352297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:09:24
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 20:42:44

US3352297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:09:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Mar 2021 20:42:44

US3352297

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered 'OLD57'	System	16 Mar 2021 20:42:44

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '11:00'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered '16 Mar 2021 11:00'	System	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '37.0' C	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '55'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered 'bpm'	System	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '12'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered 'breaths/min'	System	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '122'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered 'mmHg'	System	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:02
User entered '72'	(b) (4), (b) (6)	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered 'mmHg'	System	16 Mar 2021 20:43:15

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43

US3352297

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43

US3352297

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:11
User closed query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, in Visit 4 Day 209 "Was the physical examination performed?" is recorded as yes with date as '16 March 2021' but in OL-D57 ' Was the physical examination performed?' is recorded as 'no' and date is also blank. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:40:03
Query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, in Visit 4 Day 209 "Was the physical examination performed?" is recorded as yes with date as '16 March 2021' but in OL-D57 ' Was the physical examination performed?' is recorded as 'no' and date is also blank. Please clarify why there is a difference or update the field. Thank you!' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 17:17:11
User opened query 'Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, in Visit 4 Day 209 "Was the physical examination performed?" is recorded as yes with date as '16 March 2021' but in OL-D57 ' Was the physical examination performed?' is recorded as 'no' and date is also blank. Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:04:26
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 20:43:22

US3352297

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:11
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 20:43:22

US3352297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 20:43:37

US3352297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:19
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 20:43:37

US3352297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:10:19
User entered '11:07'	(b) (4), (b) (6)	16 Mar 2021 20:43:37

US3352297

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:43
User entered '16 Mar 2021 11:07'	System	16 Mar 2021 20:43:37

US3352297

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:12:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:04:02
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:10:15

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:22:56
User entered 'USA-US066-2021-mRNA-1273-P301000005'	System	27 Jan 2021 19:22:43
User entered 'New'	(b) (4), (b) (6)	27 Jan 2021 19:22:43

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Injury to hand NOS - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 17:12:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 17:12:49
Data point term sent to Coder	System	26 Jan 2021 17:12:00
User entered 'LEFT HAND TRAUMA'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:17:29
User closed query 'Please clarify per source AE log this is 20JAN2021' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:17:21
Query 'Please clarify per source AE log this is 20JAN2021' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	11 Mar 2021 19:01:29
DataPoint Un-verified.	Matthew Muniz (b) (4)	11 Mar 2021 18:59:37
User entered '20 Jan 2021' reason for change: Data Entry Error	Matthew Muniz (b) (4)	11 Mar 2021 18:59:37
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User opened query 'Please clarify per source AE log this is 20JAN2021' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:29:53
User entered '19 Jan 2021' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 14:32:46
User entered '21 Jan 2021'	Yulexis Amestoy (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:11:56

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US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:24:12
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 19:29:46
User entered 'No (N)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	17 Mar 2021 19:29:46
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Mar 2021 19:28:58
DataPoint Un-verified.	Matthew Muniz (b) (4)	11 Mar 2021 18:59:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	11 Mar 2021 18:59:37
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:39:16
User closed query 'Please clarify per source this is ongoing. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:17:26
Query 'Please clarify per source this is ongoing. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	17 Mar 2021 19:29:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Mar 2021 19:28:58
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Mar 2021 19:28:58
User entered '18 Feb 2021' reason for change: New Information	Matthew Muniz (b) (4)	17 Mar 2021 19:28:58
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Mar 2021 18:59:37
DataPoint Un-verified.	Matthew Muniz (b) (4)	11 Mar 2021 18:59:37
User entered empty; reason for change New Information	Matthew Muniz (b) (4)	11 Mar 2021 18:59:37
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User opened query 'Please clarify per source this is ongoing. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:08:05
User entered '11 Feb 2021' reason for change: New Information	Surisaday Mederos (b) (4)	12 Feb 2021 14:51:06
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Feb 2021 14:32:46
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Feb 2021 14:32:46
User entered '23 Jan 2021' reason for change: New Information	Surisaday Mederos (b) (4)	12 Feb 2021 14:32:46

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). User entered '21 Jan 2021'	System  Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56  26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 17:11:56

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US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'Grade 4 (Grade 4)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '1'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User closed query 'PV Query: Please confirm hospital admission date as it is prior to onset of event. Please update if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 19:06:57
Query 'PV Query: Please confirm hospital admission date as it is prior to onset of event. Please update if applicable.' answered with 'Admission date was 20 January 2021 according to medical records.' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:56:47
User entered '20 Jan 2021' reason for change: New Information	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:32:46
User opened query 'PV Query: Please confirm hospital admission date as it is prior to onset of event. Please update if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:16:32
User entered '19 Jan 2021'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:15:18
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 13:42:14
User entered '23 Jan 2021' reason for change: New Information	Surisaday Mederos (b) (4)	12 Feb 2021 14:51:06
User entered '22 Jan 2021'	Yulexis Amestoy (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User closed query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:19:22
Query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' answered with 'Not related to investigational product.' (Site from DM).	Surisaday Mederos (b) (4)	12 Feb 2021 14:55:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	12 Feb 2021 14:32:46
User opened query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:12:20
User entered 'Not Applicable (NOT APPLICABLE)'	Yulexis Amestoy (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 19:07:07
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' answered with 'Not related ' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:54:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:32:46
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:15:57
User entered 'Not Applicable (NOT APPLICABLE)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'None (NONE)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Feb 2021 18:32:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Jan 2021 17:11:56
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:17:35
User closed query 'Per ConMED Log Subject had ConMeds for event. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:17:34
Query 'Per ConMED Log Subject had ConMeds for event. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	17 Mar 2021 19:30:10
DataPoint Un-verified.	Matthew Muniz (b) (4)	17 Mar 2021 19:28:58
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	17 Mar 2021 19:28:58
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User opened query 'Per ConMED Log Subject had ConMeds for event. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:31:28
User entered '0'	Yulexis Amestoy (b) (4)	26 Jan 2021 17:11:56
	(b) (4)	

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Feb 2021 18:32:28
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:32:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
Query 'PV Query: Please confirm what trauma on the left hand was repaired.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:14:37
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:08
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)	16 Feb 2021 19:07:20
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)	16 Feb 2021 19:07:14
User opened query 'PV Query: Please confirm what trauma on the left hand was repaired.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 13:41:48
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 'SARS-CoV 2 not detected 20 January 21' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:54:12
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 'x ray hand left lateral and oblique performed 20 January 21' (Site from Safety).	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:53:39
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Feb 2021 14:51:06

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Feb 2021 14:51:06
User entered 'Subject went to the hospital after an injury to his left hand. He was powerwashing the roof of his car when his left hand slipped and the powerwasher gun nozzle hit the back of his left hand.' reason for change: New Information	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 14:51:06
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)	04 Feb 2021 19:16:18
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)	04 Feb 2021 19:16:08
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Jan 2021 17:11:56
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:11:56

US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 17:11:56

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US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 17:11:56

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US3352297

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:12:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 17:11:56

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US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:12:18

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
User closed query 'Per source please enter ConMed Polysporin for left hand trauma with start date of 30JAN21, this was not added ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 19:25:26
Query 'Per source please enter ConMed Polysporin for left hand trauma with start date of 30JAN21, this was not added ' answered with 'data verified and entered ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 16:28:05
User opened query 'Per source please enter ConMed Polysporin for left hand trauma with start date of 30JAN21, this was not added ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 16:36:28
User closed query 'Per source please enter ConMed Polysporin for left hand trauma with start date of 30JAN21. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 16:36:28
Query 'Per source please enter ConMed Polysporin for left hand trauma with start date of 30JAN21. ' answered with 'added updated' (Site from CRA).	Matthew Muniz (b) (4)	19 Mar 2021 20:36:51
User opened query 'Per source please enter ConMed Polysporin for left hand trauma with start date of 30JAN21. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:07:24
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 17:51:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:39:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:27:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:27:45
Data point term sent to Coder	System	01 Sep 2020 17:41:36
User entered 'ASPIRIN'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'CARDIAC PROFHYLAXIS'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '81'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'UN UNK 1998'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:40:43

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:12:18**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:40:43

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US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:40:43

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US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 17:40:43

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US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:01:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:01:47
Data point term sent to Coder	System	26 Jan 2021 17:15:03
User entered 'CEPHALEXIN'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:11:53
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'as stated cephalixin taken for left hand repair ' (Site from DM).	Matthew Muniz (b) (4)	19 Mar 2021 20:32:59
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:42:41
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'LEFT HAND REPAIR'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '500'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'mg (mg)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'four times daily (QID)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Oral (ORAL)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '22 Jan 2021'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Feb 2021 18:26:15
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '16 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	23 Feb 2021 18:26:15
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:14:28

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:12:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User entered '4'	System	26 Jan 2021 17:14:28

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User entered '1'	System	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:17
User entered '804 (804)'	System	26 Jan 2021 17:14:28

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXI CLAV - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 23:55:53
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 Jan 2021 23:55:53
Data point term sent to Coder	System	26 Jan 2021 17:16:10
User entered 'AMOX-CLAV'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'LEFT HAND REPAIR'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '875/125'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'mg (mg)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'twice daily (BID)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Oral (ORAL)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '22 Jan 2021'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)' reason for change: New Information	Surisaday Mederos (b) (4)	12 Feb 2021 15:00:20
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '27 Jan 2021' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 15:00:20
User entered empty.	Yulexis Amestoy (b) (4)	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:15:37

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:12:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User entered '2'	System	26 Jan 2021 17:15:37

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User entered '1'	System	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:19
User entered '804 (804)'	System	26 Jan 2021 17:15:37

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: BOOSTRIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:32:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:32:56
Data point term sent to Coder	System	12 Feb 2021 15:16:25
User entered 'Boostrix'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Left hand trauma'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0.5'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'mL (mL)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:15:51
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '20 Jan 2021'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '20 Jan 2021'	Surisaday Mederos (b) (4)	12 Feb 2021 15:15:51
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:15:51

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:12:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User entered empty.	System	12 Feb 2021 15:15:51

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User entered empty.	System	12 Feb 2021 15:15:51

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:22
User entered empty.	System	12 Feb 2021 15:15:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:34:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:34:47
Data point term sent to Coder	System	12 Feb 2021 15:19:27
User entered 'Zosyn'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:18:31
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Left hand trauma'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '3.375' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 15:25:48
User entered '100'	Surisaday Mederos (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'g (g)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 15:26:55
User entered 'Other (OTHER)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 15:25:48
User entered 'mL (mL)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	12 Feb 2021 15:26:55
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	12 Feb 2021 15:25:48
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'once daily (QD)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '20 Jan 2021'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '21 Jan 2021'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User entered '1'	System	12 Feb 2021 15:18:31

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User entered '1'	System	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:25
User entered '804 (804)'	System	12 Feb 2021 15:18:31

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:02:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:02:45
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:15:42
Data point term sent to Coder	System	12 Feb 2021 15:20:28
User entered 'Sodium Chloride'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Left hand trauma'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '10' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 15:25:01
User entered '10-30'	(b) (4)	
	Surisaday Mederos (b) (4)	12 Feb 2021 15:19:51
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'mL (mL)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:19:51
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	12 Feb 2021 15:20:13
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	12 Feb 2021 15:20:13
User entered 'once daily (QD)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Feb 2021 15:20:13
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
User entered 'once (ONCE)'	System	12 Feb 2021 15:19:51
	Surisaday Mederos (b) (4)	12 Feb 2021 15:19:51
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '20 Jan 2021'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered '21 Jan 2021'	Surisaday Mederos (b) (4)	12 Feb 2021 15:19:51
	(b) (4)	

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:49
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	12 Feb 2021 15:19:51

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:12:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User entered '1'	System	12 Feb 2021 15:20:13
User entered empty.	System	12 Feb 2021 15:19:51

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User entered '1'	System	12 Feb 2021 15:20:13
User entered empty.	System	12 Feb 2021 15:19:51

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:12:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:29
User entered '804 (804)'	System	12 Feb 2021 15:20:13
User entered empty.	System	12 Feb 2021 15:19:51

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;POLYMYXIN B SULFATE, PRODUCTSYNONYM: POLYSPORIN [BACITRACIN;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:24:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:24:51
Data point term sent to Coder	System	01 Apr 2021 19:35:27
User entered 'Polysporin'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'Left Hand Trauma'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered '1'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'application'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered '30 Jan 2021'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered '18 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:22:33
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:34:45

US3352297

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:12:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User entered '2'	System	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User entered '1'	System	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:57:32
User entered '804 (804)'	System	01 Apr 2021 19:34:45

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:12:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:40
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
User closed query 'Per source subject also had and Lateral and oblique X-Ray of left hand. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:17:52
Query 'Per source subject also had and Lateral and oblique X-Ray of left hand. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	17 Mar 2021 19:19:32
User opened query 'Per source subject also had and Lateral and oblique X-Ray of left hand. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:14:53
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:15
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:12:49

US3352297

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:12:18**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:36
User entered '21 Jan 2021'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:13:25

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:36
User entered 'LEFT HAND REPAIR'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:13:25

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:36
User closed query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:15:10
Query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	06 Feb 2021 18:32:44
User opened query 'Per CDM: Indication = Adverse Event, however none of the AE's recorded has the 'Concomitant procedure' option checked. Please reconcile and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:07:08
User entered 'Adverse Event (AE)'	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:13:25

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:12:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:10:36
User entered empty.	Yulexis Amestoy (b) (4) (b) (4)	26 Jan 2021 17:13:25

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:38:09
User entered '20 Jan 2021'	Matthew Muniz (b) (4)	17 Mar 2021 19:19:18

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:38:09
User entered 'xray hand left lateral and oblique'	Matthew Muniz (b) (4)	17 Mar 2021 19:19:18

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:38:09
User entered 'Adverse Event (AE)'	Matthew Muniz (b) (4)	17 Mar 2021 19:19:18

US3352297

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:12:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:38:09
User entered empty.	Matthew Muniz (b) (4)	17 Mar 2021 19:19:18

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'USA-US066-2021-MRNA-1273-P301000005'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Howard'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'schwartz'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '7265 SHeridan Street SUite 210'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Pembroke Pines'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'FL'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '33024'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'US'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 12:14:28
User entered '4'	System	12 Mar 2021 13:32:45
User entered '3'	System	16 Feb 2021 19:08:26
User entered '2'	System	08 Feb 2021 14:05:55
User entered '1'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'USA-US066-2021-MRNA-1273-P301000005'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Howard'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'schwartz'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '7265 SHeridan Street SUite 210'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Pembroke Pines'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'FL'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '33024'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'US'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 12:14:28
User entered '4'	System	12 Mar 2021 13:32:45
User entered '3'	System	16 Feb 2021 19:08:26
User entered '2'	System	08 Feb 2021 14:05:55
User entered '1'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:12:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
User entered '27/Jan/2021 14:23'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:12:18

**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.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'l'	(b) (4), (b) (6)	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'USA-US066-2021-MRNA-1273-P301000005'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Howard'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'schwartz'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '7265 SHeridan Street SUite 210'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Pembroke Pines'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'FL'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '33024'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'US'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 12:14:28
User entered '4'	System	12 Mar 2021 13:32:45
User entered '3'	System	16 Feb 2021 19:08:26
User entered '2'	System	08 Feb 2021 14:05:55
User entered '1'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:12:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
User entered '08/Feb/2021 09:05'	System	08 Feb 2021 14:05:55

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:12:18

**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.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 19:08:10
User entered '1'	(b) (4), (b) (6)	08 Feb 2021 14:05:55

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'USA-US066-2021-MRNA-1273-P301000005'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Howard'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'schwartz'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '7265 SHeridan Street SUite 210'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Pembroke Pines'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'FL'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '33024'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'US'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 12:14:28
User entered '4'	System	12 Mar 2021 13:32:45
User entered '3'	System	16 Feb 2021 19:08:26
User entered '2'	System	08 Feb 2021 14:05:55
User entered '1'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:12:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
User entered '16/Feb/2021 14:08'	System	16 Feb 2021 19:08:26

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:12:18

**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.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:14:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 19:08:26

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'USA-US066-2021-MRNA-1273-P301000005'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Howard'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'schwartz'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '7265 SHeridan Street SUite 210'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Pembroke Pines'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'FL'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '33024'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'US'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 12:14:28
User entered '4'	System	12 Mar 2021 13:32:45
User entered '3'	System	16 Feb 2021 19:08:26
User entered '2'	System	08 Feb 2021 14:05:55
User entered '1'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:12:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:39:40
User entered '12/Mar/2021 08:32'	System	12 Mar 2021 13:32:45

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:12:18

**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.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:39:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:14:16
User entered '1'	(b) (4), (b) (6)	12 Mar 2021 13:32:45

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'USA-US066-2021-MRNA-1273-P301000005'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Yes (Y)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'No (N)'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Howard'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'schwartz'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '7265 SHeridan Street SUite 210'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'Pembroke Pines'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered 'FL'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 19:23:07
User entered '33024'	System	27 Jan 2021 19:22:43

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 14:05:46
User entered 'US'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 12:14:28
User entered '4'	System	12 Mar 2021 13:32:45
User entered '3'	System	16 Feb 2021 19:08:26
User entered '2'	System	08 Feb 2021 14:05:55
User entered '1'	System	27 Jan 2021 19:23:15

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:12:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:39:40
User entered '18/Mar/2021 12:14'	System	18 Mar 2021 12:14:28

US3352297

Folder: SAE USA-US066-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:12:18

**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.	Howard schwartz (b) (4)	28 Apr 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:39:40
User entered '1'	(b) (4), (b) (6)	18 Mar 2021 12:14:28