

US3172028 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:33:24

All time stamps listed in this document are displayed in GMT

US3172028

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 14:55:54

Generated On: 09 Jun 2021 15:33:24

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Participant ID

US3172028

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

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US3172028

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 11 AUG 2020

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

Folder OID SCRN

US3172028

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3172028

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Date of Informed Consent (*dd MMM yyyy*) 11 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

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

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

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

Enrollment Trigger 1

US3172028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3172028

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	



US3172028

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	THIAMINE DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172028

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172028

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

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

US3172028

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	PAST TOBACCO USER
Start date (dd MMM yyyy)	UN UNK 1982
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	ALCOHOL CONSUMPTION
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	CAFFEINE CONSUMPTION
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	DYSLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3172028

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3172028

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Condition	COCAINE ABUSE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3172028

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:31 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 08:31
Height ( <i>xxx.x</i> )	178.0 cm
Weight ( <i>xxx.x</i> )	94.3 kg
BMI ( <i>xxx.x</i> )	29.76266 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) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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.*

US3172028

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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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) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 11 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 143278

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Height	ND - Not Done
Weight	ND - Not Done

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	08:31 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 08:31
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:20
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3172028

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3172028

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 10:50

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

US3172028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 AUG 2020
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Collection time (00:00-23:59)	09:47 (24 HR)
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Collection date and time (derived)	11 AUG 2020 09:47
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US3172028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:44	11 AUG 2020 09:44
Nasopharyngeal Swab 2	No		

US3172028

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 11:23

PC Open Date & Time

11 AUG 2020 11:10

PC Close Date & Time

11 AUG 2020 13:40

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 AUG 2020 19:11
PC Open Date & Time	11 AUG 2020 14:35
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

12 AUG 2020 12:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:53

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 12:20

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

15 AUG 2020 12:21

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:10

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 14:49

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 11:24

PC Open Date & Time

11 AUG 2020 11:10

PC Close Date & Time

11 AUG 2020 13:40

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**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

11 AUG 2020 19:11

PC Open Date & Time

11 AUG 2020 14:35

PC Close Date & Time

12 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:54

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:20

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:22

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:10

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**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

17 AUG 2020 14:50

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**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 ☐

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 11:25
PC Open Date & Time	11 AUG 2020 11:10
PC Close Date & Time	11 AUG 2020 13:40

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**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 ☐

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 19:12
PC Open Date & Time	11 AUG 2020 14:35
PC Close Date & Time	12 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:39
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

54 of 2633

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:54
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**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 ☒

PRODUCTION RELEASE (v12.003

56 of 2633

EAB) (1725)

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

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

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2633

EAB) (1725)

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:22
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2633

EAB) (1725)

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:11
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**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 ☒

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 14:50
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59



US3172028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172028

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 08:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG



US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:29
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3172028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 10:49

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

US3172028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	8 SEP 2020
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Collection time (00:00-23:59)	10:06 (24 HR)
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Collection date and time (derived)	8 SEP 2020 10:06
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US3172028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:04	8 SEP 2020 10:04
Nasopharyngeal Swab 2	No		

US3172028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**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

08 SEP 2020 11:20

PC Open Date & Time

08 SEP 2020 11:09

PC Close Date & Time

08 SEP 2020 13:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.6 °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	08 SEP 2020 22:40
PC Open Date & Time	08 SEP 2020 14:34
PC Close Date & Time	09 SEP 2020 11:59



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:32

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

11 SEP 2020 06:25

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 SEP 2020 16:41

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**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.

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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

13 SEP 2020 12:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**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

08 SEP 2020 11:21

PC Open Date & Time

08 SEP 2020 11:09

PC Close Date & Time

08 SEP 2020 13:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**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

08 SEP 2020 22:40

PC Open Date & Time

08 SEP 2020 14:34

PC Close Date & Time

09 SEP 2020 11:59



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:32

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 06:25

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 16:41

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 12:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**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

14 SEP 2020 12:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**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 ☐

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:21
PC Open Date & Time	08 SEP 2020 11:09
PC Close Date & Time	08 SEP 2020 13:39



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**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 ☐

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 22:41
PC Open Date & Time	08 SEP 2020 14:34
PC Close Date & Time	09 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**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 ☒

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:33
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2633

EAB) (1725)

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 06:26
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2633

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 16:41
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**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 ☒

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:34
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**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 ☒

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:13
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

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 ☒

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

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

US3172028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

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*

US3172028

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	06 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 11:29
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

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.*

US3172028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	06 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:51 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	06 OCT 2020 11:51
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US3172028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 06:37:52

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 00:04:04

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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

25 OCT 2020 07:18:48

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 07:00:01

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:01:59

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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

22 NOV 2020 00:08:26

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 07:18:02

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 07:57:46

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 04:07:22
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 01:04:32

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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

24 DEC 2020 07:20:27

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 04:33:09

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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

07 JAN 2021 23:03:26

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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

14 JAN 2021 00:02:07

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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 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	21 JAN 2021 06:51:31
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 05:59:09

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 00:01:50

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 07:00:56

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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	18 FEB 2021 05:14:14
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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

25 FEB 2021 11:56:31

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 06:05:34

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 05:56:32

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 06:25:35

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:07:55

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 03:41:51

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 05:47:29

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 06:05:35

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:02:43

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

Date and time of submission

29 APR 2021 00:02:23

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 MAY 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2021 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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12 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 AUG 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 376

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

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

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59
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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 481

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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23 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 DEC 2021 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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28 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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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2022 23:59



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

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

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 ☐

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

10 OCT 2022 23:59

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US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172028**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3172028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:33:24

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		04 MAR 2021 06:06:04

US3172028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3172028

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:56:16

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID VISIT4



US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

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

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

US3172028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

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.*

US3172028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

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*

**US3172028**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3172028

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:33:24

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"/>

**US3172028**

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

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

**Generated On: 09 Jun 2021 15:33:24**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3172028

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 28 JAN 2021

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

Folder OID UNBLND\_DECIDE

US3172028

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Date of updated informed consent (dd MMM yyyy)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	28 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

US3172028

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Height	ND - Not Done
Weight	093.2 kg
BMI (xxx.x)	

US3172028

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Height	ND - Not Done
Weight	093.2 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 09:50
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3172028

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Height	ND - Not Done
Weight	093.2 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 11:52
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3172028

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

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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



US3172028

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

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

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) 12 MAR 2021

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 11:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3172028

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	28 JAN 2021
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Collection time (00:00-23:59)	11:26 (24 HR)
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Collection date and time (derived)	28 JAN 2021 11:26
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US3172028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	28 JAN 2021
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Collection time (00:00 - 23:59)	11:27
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Collection Date and Time (derived)	28 JAN 2021 11:27
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US3172028

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

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

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

US3172028

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	12 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

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)	12 APR 2021
Time of assessment (00:00-23:59)	07:36 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 07:36
Temperature (xxx.x)	36.7 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG



US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 10:26
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3172028

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

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.*

US3172028

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

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) 12 APR 2021

What was the treatment time? (00:00-23:59) 09:56 (24 HR)

Treatment Date and Time (derived) 12 APR 2021 09:56

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

US3172028

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172028

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172028

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3172028**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3172028

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	



US3172028

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

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.*

**US3172028**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:33:24**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3172028

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 14:55:54

Generated On: 09 Jun 2021 15:33:24

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID	USA-US118-2021-MRNA-1273-P30 1000001
Adverse event	CARDIAC ARRHYTHMIA PAROXYSMAL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	12 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

SUBJECT WAS HOSPITALIZED  
DUE TO COMPLICATION OF  
CARDIAC ARRHYTHMIA  
MANIFESTED WITH  
PALPITATION STARTED ON  
08DEC2020 SINCE 23:42.  
SUBJECT DENIES CHEST PAIN  
OR SHORTNESS OF BREATHE.  
AT ER EKG'S SHOW EVIDENCE  
OF RAPID A.F.S. EKG RESULTS:  
SINUS RHYTHM WITH FREQUENT  
VENTRICULAR PREMATURE  
COMPLEXES , LEFT ATRIAL  
ENLARGEMENT, MODERATE ST  
DEPRESSION, ABNORMAL ECG  
PVE AND HYPOMAGNESEMIA.  
SUBJECT WITH HISTORY OF  
HYPERTENSION, DIABETES  
TYPE II, ALCOHOL AND  
COCAINE. ON ADMISSION  
SUBJECT WAS TESTED FOR  
TOX SCREEN AND IT WAS  
POSITIVE FOR BENZODIAPEM  
AND COCAINE. PATIENT  
STARTED WITH  
ANTICOAGULANT, ELIQUIS  
5MG TWICE A DAY AND  
DILTIAZEM 180MG FOR RATE  
CONTROL. ON 08DEC2020 A  
CHEST SINGLE VIEW WAS  
PERFORMED AND THE  
IMPRESSION WAS NO ACUTE  
ABNORMALITY. ON PHYSICAL  
EXAM SUBJECT WAS ALERT,  
WELL NOURISHED NO ACUTE  
DISTRESS. SARS-COV-2  
COVID-19 SCREENING DONE  
08DEC2020 RESULTS NOT  
DETECTED.

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

US3172028

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID

Adverse event

CARDIAC ARRHYTHMIA  
PAROXYSMAL

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)

05 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID	USA-US118-2021-MRNA-1273-P30 1000014
Adverse event	CARDIAC ARRHYTHMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 APR 2021
Hospital Discharge Date (dd MMM yyyy)	06 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

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ON PHONE CALL 239 DAY  
SUBJECT REFERRED BEEN AT  
BAPTIST HOSPITAL DUE TO  
ANOTHER EPISODE OF  
CARDIAC ARRHYTHMIA. FROM  
05APR2021 TO 06APR2021. HE  
WAS DISCHARGED BY 4 PM.  
SUBJECT HAD ANOTHER  
CARDIAC ARRHYTHMIA  
EPISODE "LIKE HE HAD  
BEFORE" REASON WHY HE  
DECIDED TO GO TO THE ER. HE  
RECEIVED TREATMENT. HE  
DOESNT RECALL THE NAME  
OF THE MEDICATION AND HE  
WAS PRESCRIBED WITH NEW  
MEDICATION THAT HE PLACED  
AT THE PHARMACY. PENDING  
REPORT INFORMATION.  
MEDICAL RECORDS WILL BE  
REQUESTED.

---

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

---

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID

Adverse event

WORSENING OF  
HYPERTENSION

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)

08 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID

Adverse event

THIAMINE DEFICIENCY

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)

08 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID

Adverse event

WORSENING OF DIABETES

TYPE 2

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)

08 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

AEID	
Adverse event	HYPOMAGNESEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:55:54

Generated On: 09 Jun 2021 15:33:24

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 14:55:55

Generated On: 09 Jun 2021 15:33:24

---

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

Yes ☒

No ☐

---

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

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US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	10 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

BED TIME

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication DILTIAZEM

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication CLOPIDROGEL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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Name of Medication FOLIC ACID

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 05 APR 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication CARDIAC HEART FAILURE

Dose per administration 3.125

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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	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)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIOVASCULAR DISEASE  
PRECAUTION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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Name of Medication GLIMIPERIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	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)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication ELIQUIS

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS ATRIAL  
FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:26:00

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Name of Medication SIMVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

DAILY FOR 30 DAYS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	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)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication JARDINACE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING DIABETES TYPE II

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	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)		08 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication CT SCAN TEST

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		SUB LINGUAL
Start date (dd MMM yyyy)	09 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication IODINE (80ML)

Prophylaxis Yes ☐  
No ☒

Indication COMPUTED TOMOGRAPHY

Dose per administration 300/309

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	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)		09 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication LEXISCAN

Prophylaxis Yes ☐  
No ☒

Indication NUCLEAR MYOCARDIA SECT

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	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)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication THIAMINE

Prophylaxis Yes ☐  
No ☒

Indication THIAMINE DEFICIENCY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES - 2ND DOSE - SARS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:26:00

Generated On: 09 Jun 2021 15:33:24

	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)		13 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 14:39:11

Generated On: 09 Jun 2021 15:33:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 15:55:55

Generated On: 09 Jun 2021 15:33:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 DEC 2020	CARDIAC CATH PROCEDURE	Adverse Event	
8 DEC 2020	EKG-STRESS	Adverse Event	
5 DEC 2020	RADIOLOGY CHEST SINGLE VIEW XR	Adverse Event	
10 DEC 2020	MYOCARDIAL SPECT MULT W EF WM	Adverse Event	
9 DEC 2020	RADIOLOGY: CORONARY CTA W CA SCORE \T\ FUNC	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:33:24

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:33:24

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 ☐



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Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

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Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	06/JAN/2021 10:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/FEB/2021 16:25
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

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/MAR/2021 10:23
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

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/APR/2021 06:16
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

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/APR/2021 10:38
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

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	14/APR/2021 00:10
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

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/APR/2021 06:22
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



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 15:55:56

Generated On: 09 Jun 2021 15:33:24

SAEID	USA-US118-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	13/APR/2021 10:55
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

US3172028 (Prod: Suncoast Research Group LLC - ERN-PPDS)

**US3172028**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:33:24**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'US3172028'	RWS_ENDPOINT	11 Aug 2020 12:14:23
	ENDPOINT (b) (4)	
	(b) (4)	

US3172028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 14:54:59
	(b) (4)	

US3172028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '11 AUG 2020'	(b) (4)	
	RWS_ENDPOINT	11 Aug 2020 12:14:24
	ENDPOINT (b) (4)	
	(b) (4)	

US3172028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	11 Aug 2020 14:54:59
	(b) (4)	

**US3172028**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'SCRN'	System	11 Aug 2020 14:54:59



US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 12:14:25

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '54'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'YEARS'	System	11 Aug 2020 14:59:36

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '54'	System	11 Aug 2020 14:55:11

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Male (M)'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'I'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	



US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:36
	(b) (4)	

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 14:55:11
	(b) (4)	



**US3172028**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Aug 2020'	System	11 Aug 2020 14:55:11

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2020'	System	11 Aug 2020 14:55:11

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Amendment 1 (1)'	Mariete Rendon (b) (4)	11 Aug 2020 14:55:11
	(b) (4)	

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 14:55:11
	(b) (4)	

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:55:11
	(b) (4)	

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:55:11
	(b) (4)	

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:55:11
	(b) (4)	

US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	RWS_ENDPOINT	11 Aug 2020 12:14:24
	ENDPOINT (b) (4)	
	(b) (4)	



US3172028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'I'	System	11 Aug 2020 14:55:35

US3172028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 14:55:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:33:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:00:49
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:04:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:04:10
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 15:03:05
User entered 'Presbyopia'	Mariete Rendon (b) (4)	11 Aug 2020 15:02:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'UN UNK 2015'	Mariete Rendon (b) (4)	11 Aug 2020 15:02:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:02:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:02:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:02:12
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:02:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2015'	System	11 Aug 2020 15:02:12

**US3172028**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2015'	System	11 Aug 2020 15:02:12

**US3172028**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	11 Aug 2020 15:02:12

**US3172028**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	11 Aug 2020 15:02:12

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	22 Apr 2021 15:55:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B1 deficiency, LLT: Vitamin B1 deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:42:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:42:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B1 deficiency, LLT: Vitamin B1 deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:41:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:41:44
Data point term sent to Coder	System	14 Apr 2021 13:41:40
User closed query 'Per CDM Coding: for term THEANINE DYCICALIN, Please update the term with further information for a more specific meaning/diagnosis. Please clarify if that was Drug allergy or Amino acid supplementation etc.' (Site from System).	System	14 Apr 2021 13:40:56
Query 'Per CDM Coding: for term THEANINE DYCICALIN, Please update the term with further information for a more specific meaning/diagnosis. Please clarify if that was Drug allergy or Amino acid supplementation etc.' answered with 'Data updated' (Site from System).	Mariete Rendon (b) (4) (b) (4)	14 Apr 2021 13:40:56
Data point term sent to Coder	System	14 Apr 2021 13:40:35
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	14 Apr 2021 13:40:25
User entered 'Thiamine Deficiency' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Apr 2021 13:40:25

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
User opened query 'Per CDM Coding: for term THEANINE DYCICALIN, Please update the term with further information for a more specific meaning/diagnosis. Please clarify if that was Drug allergy or Amino acid supplementation etc.' (Site from System).	Coder Import (b) (4)	30 Mar 2021 14:25:59
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
Data point term sent to Coder	(b) (4)	
User closed query 'CDM Coding: For the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).	System	26 Feb 2021 14:23:35
' (Site from System).	System	26 Feb 2021 14:23:31
Query 'CDM Coding: For the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).	Jessie Downs (b) (4)	26 Feb 2021 14:23:31
' answered with 'data updated with new medical history.' (Site from System).	(b) (4)	
Coding entries removed.	Jessie Downs (b) (4)	26 Feb 2021 14:23:09
User entered 'theanine dycicalin' reason for change:	(b) (4)	
Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 14:23:09
DataPoint activated with code reason code Data required.	(b) (4)	
User opened query 'CDM Coding: For the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
' (Site from System).	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	11 Nov 2020 05:03:46
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	System	02 Sep 2020 22:12:22
	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
User closed query 'CDM-Coding: Please enter the type of CHEST PAIN [Chest pain – cardiac or Non-cardiac chest pain or Musculoskeletal Chest Pain] in order that the term may be coded accurately. Please make your changes to the reported term. ' (Site from System).	System	02 Sep 2020 22:11:20
Query 'CDM-Coding: Please enter the type of CHEST PAIN [Chest pain – cardiac or Non-cardiac chest pain or Musculoskeletal Chest Pain] in order that the term may be coded accurately. Please make your changes to the reported term. ' answered with 'Data entered in error' (Site from System).	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 22:11:20
User opened query 'CDM-Coding: Please enter the type of CHEST PAIN [Chest pain – cardiac or Non-cardiac chest pain or Musculoskeletal Chest Pain] in order that the term may be coded accurately. Please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	02 Sep 2020 08:33:38
Data point term sent to Coder	System	28 Aug 2020 21:10:01
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	28 Aug 2020 21:09:50
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'ERROR IN DATA ENTRY. PATIENT WITH MEDICAL HISTORY OF HYPERTENSION. HYPERTENSION WAS UPDATED IN MEDICAL HISTORY.' (Site from System).	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 21:09:50
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:14:19

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:08:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:08:09
Data point term sent to Coder	System	11 Aug 2020 15:07:17
User entered 'Chest Pain'	Mariete Rendon (b) (4)	11 Aug 2020 15:06:56
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'UN UNK 2018' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 14:23:09
	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered 'UN UNK 2010'	Mariete Rendon (b) (4)	11 Aug 2020 15:06:56
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:06:56
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:06:56
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:06:56
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:06:56
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2018'	System	26 Feb 2021 14:23:09
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered 'Jan 2010'	System	11 Aug 2020 15:06:56

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2018'	System	26 Feb 2021 14:23:09
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
User entered '2010'	(b) (4)	
	System	11 Aug 2020 15:06:56



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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered empty.	System	11 Aug 2020 15:06:56

US3172028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	26 Feb 2021 14:22:55
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	02 Sep 2020 22:11:44
	(b) (4)	
User entered empty.	System	11 Aug 2020 15:06:56

US3172028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:09:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:09:11
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 15:08:22
User entered 'Diabetes type 2'	Mariete Rendon (b) (4)	11 Aug 2020 15:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'UN UNK 2010'	Mariete Rendon (b) (4)	11 Aug 2020 15:07:35
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:07:35
	(b) (4)	



**US3172028**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2010'	System	11 Aug 2020 15:07:35

**US3172028**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2010'	System	11 Aug 2020 15:07:35

**US3172028**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	11 Aug 2020 15:07:35

**US3172028**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	11 Aug 2020 15:07:35

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:07:39
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 21:06:54
User entered 'HYPERTENSION'	Jessie Downs (b) (4)	28 Aug 2020 21:06:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'UN UNK 2010'	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:06:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:06:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:06:12
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:06:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:06:12
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2010'	System	28 Aug 2020 21:06:12

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2010'	System	28 Aug 2020 21:06:12

US3172028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	28 Aug 2020 21:06:12

**US3172028**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	28 Aug 2020 21:06:12

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User coded data point as SOC: Social circumstances, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-tobacco user - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:08:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:08:40
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 21:07:56
User entered 'PAST TOBACCO USER'	Jessie Downs (b) (4)	28 Aug 2020 21:07:08
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'UN UNK 1982'	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:07:08
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:07:08
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'No (N)'	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:07:08
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'UN UNK 2019'	Jessie Downs (b) (4)	28 Aug 2020 21:07:08
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:07:08
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 1982'	System	28 Aug 2020 21:07:08

**US3172028**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '1982'	System	28 Aug 2020 21:07:08

US3172028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2019'	System	28 Aug 2020 21:07:08

**US3172028**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2019'	System	28 Aug 2020 21:07:08



US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User coded data point as SOC: Social circumstances, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:08:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:08:40
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 21:07:56
User entered 'ALCOHOL CONSUMPTION'	Jessie Downs (b) (4)	28 Aug 2020 21:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'UN UNK 1982'	Jessie Downs (b) (4)	28 Aug 2020 21:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:07:35
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 1982'	System	28 Aug 2020 21:07:35

**US3172028**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '1982'	System	28 Aug 2020 21:07:35



**US3172028**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	28 Aug 2020 21:07:35

**US3172028**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	28 Aug 2020 21:07:35

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Caffeine consumption, LLT: Caffeine consumption - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:09:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 21:09:42
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 21:08:59
User entered 'CAFFEINE CONSUMPTION'	Jessie Downs (b) (4)	28 Aug 2020 21:08:01
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'UN UNK 1974'	Jessie Downs (b) (4)	28 Aug 2020 21:08:01
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:08:01
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:08:01
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	28 Aug 2020 21:08:01
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	28 Aug 2020 21:08:01
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 1974'	System	28 Aug 2020 21:08:01

US3172028

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '1974'	System	28 Aug 2020 21:08:01

**US3172028**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	28 Aug 2020 21:08:01

**US3172028**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	28 Aug 2020 21:08:01

US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:20:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:20:03
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:18:28
User entered 'dyslipidemia'	Jessie Downs (b) (4)	26 Feb 2021 14:17:40
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'un UNK 2018'	Jessie Downs (b) (4)	26 Feb 2021 14:17:40
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:17:40
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	26 Feb 2021 14:17:40
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:17:40
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:17:40
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2018'	System	26 Feb 2021 14:17:40

**US3172028**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2018'	System	26 Feb 2021 14:17:40

**US3172028**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:17:40

**US3172028**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:17:40

US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:20:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:20:03
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:18:28
User entered 'hypercholesterolemia'	Jessie Downs (b) (4)	26 Feb 2021 14:18:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'un UNK 2018'	Jessie Downs (b) (4)	26 Feb 2021 14:18:24
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:18:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:18:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:18:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:18:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2018'	System	26 Feb 2021 14:18:24

**US3172028**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2018'	System	26 Feb 2021 14:18:24

**US3172028**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:18:24

**US3172028**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:18:24



US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 14:20:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 14:20:05
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:19:30
User entered 'Obstructive Sleep Apnea'	Jessie Downs (b) (4)	26 Feb 2021 14:19:28
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'un UNK 2018'	Jessie Downs (b) (4)	26 Feb 2021 14:19:28
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:19:28
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:19:28
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:19:28
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:19:28
	(b) (4)	

**US3172028**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2018'	System	26 Feb 2021 14:19:28

**US3172028**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:33:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2018'	System	26 Feb 2021 14:19:28



US3172028

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:19:28

**US3172028**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:19:28

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Cocaine abuse - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:35:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:35:53
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:20:31
User entered 'cocaine abuse'	Jessie Downs (b) (4)	26 Feb 2021 14:20:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'un UNK 2018'	Jessie Downs (b) (4)	26 Feb 2021 14:20:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:20:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:20:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	26 Feb 2021 14:20:24
	(b) (4)	

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:20:24
	(b) (4)	



US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'Jan 2018'	System	26 Feb 2021 14:20:24

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '2018'	System	26 Feb 2021 14:20:24

US3172028

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:33:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:20:24

**US3172028**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:33:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	26 Feb 2021 14:20:24

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '08:31'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '11 Aug 2020 08:31'	System	11 Aug 2020 15:00:26



US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '178.0' cm	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	
DataPoint set to visible.	System	11 Aug 2020 14:55:35

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '94.3' kg	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	
DataPoint set to visible.	System	11 Aug 2020 14:55:35

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
Amendment Manager: User entered '29.76266'	System	16 Sep 2020 23:51:04
User entered '29.8'	System	11 Aug 2020 15:00:26
DataPoint set to visible.	System	11 Aug 2020 14:55:35

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'kg/m2'	System	11 Aug 2020 15:00:26
DataPoint set to visible.	System	11 Aug 2020 14:55:35

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 13:08:29
Query 'Data is required. Please provide.' answered with 'PER GUIDELINES, ND' (Site from System).	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 20:53:07
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 15:00:26
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:00:26

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	



US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'bpm'	System	11 Aug 2020 15:00:26

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'breaths/min'	System	11 Aug 2020 15:00:26

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mmHg'	System	11 Aug 2020 15:00:26

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:00:26
	(b) (4)	

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mmHg'	System	11 Aug 2020 15:00:26

US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41



US3172028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41

US3172028

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 12:59:46
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:08:11
	(b) (4)	

US3172028

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 12:59:46
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 14:34:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 12:56:21
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 15:08:11
	(b) (4)	

US3172028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:24

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

US3172028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:24

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

US3172028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:24

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	



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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:24

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:59:21
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:08:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 15:08:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	11 Aug 2020 15:08:38
	(b) (4)	

US3172028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'VISIT1'	System	11 Aug 2020 15:08:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:24

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 13:34:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:28:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:28:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 13:34:41
User entered '143278' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 13:34:41
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 13:34:41
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:01
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '08:31'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '11 Aug 2020 08:31'	System	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '36.7' C	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Oral (Oral)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '77'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'bpm'	System	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '13'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'breaths/min'	System	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '139'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	11 Aug 2020 15:09:45

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '88'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	11 Aug 2020 15:09:45



US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	16 Feb 2021 14:56:17
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 16:08:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 16:08:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:08:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 15:09:45
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:07:56
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 16:08:43
User entered '11:20' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:08:43
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '11 Aug 2020 11:20'	System	11 Aug 2020 16:08:43
User entered empty.	System	11 Aug 2020 15:09:45

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '36.7' C reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '80' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'bpm'	System	11 Aug 2020 16:08:43
User entered empty.	System	11 Aug 2020 15:09:45

US3172028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '17' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'breaths/min'	System	11 Aug 2020 16:08:43
User entered empty.	System	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 18:03:53
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Aug 2020 18:03:53
User entered '139' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Aug 2020 18:03:53
	(b) (4)	
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 16:08:43
User entered '198' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	11 Aug 2020 16:08:43
User entered empty.	System	11 Aug 2020 15:09:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 18:03:53
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Aug 2020 18:03:53
User entered '88' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Aug 2020 18:03:53
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 16:08:43
User entered '134' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 16:08:43
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	11 Aug 2020 16:08:43
User entered empty.	System	11 Aug 2020 15:09:45

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 13:00:05
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 15:09:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 13:00:05
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:09:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 14:56:00

US3172028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:56:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 14:56:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 14:56:00



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 14:56:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '10:50'	Mariete Rendon (b) (4)	11 Aug 2020 14:56:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '11 Aug 2020 10:50'	System	11 Aug 2020 14:56:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 14:56:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'ONCE'	System	11 Aug 2020 14:56:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 14:56:00

US3172028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:10:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 15:10:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '09:47'	Mariete Rendon (b) (4)	11 Aug 2020 15:10:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '11 Aug 2020 09:47'	System	11 Aug 2020 15:10:23

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 15:10:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '09:44'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:10:36
	(b) (4)	

**US3172028**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '11 Aug 2020 09:44'	System	11 Aug 2020 15:10:36

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:10:36



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	16 Sep 2020 18:27:43
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:10:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	16 Sep 2020 18:27:43
	(b) (4)	
User entered '09:44'	Mariete Rendon (b) (4)	11 Aug 2020 15:10:36
	(b) (4)	

US3172028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered empty.	System	16 Sep 2020 18:27:43
User entered '11 Aug 2020 09:44'	System	11 Aug 2020 15:10:36

US3172028

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 16:08:59
	(b) (4)	

US3172028

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	11 Aug 2020 16:08:59

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:23:23', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '17f074d2-7ace-4db7-a0e0-5b93775121eb' User entered 'Yes (Y)'	System	11 Aug 2020 15:23:58
	System	11 Aug 2020 15:23:58

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:23:43', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '17f074d2-7ace-4db7-a0e0-5b93775121eb' User entered '98.1'	System	11 Aug 2020 15:23:58
	System	11 Aug 2020 15:23:58



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:23:48', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '17f074d2-7ace-4db7-a0e0-5b93775121eb' User entered 'No (N)'	System	11 Aug 2020 15:23:58
	System	11 Aug 2020 15:23:58

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:23:57', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '17f074d2-7ace-4db7-a0e0-5b93775121eb' User entered '11 Aug 2020 11:23'	System	11 Aug 2020 15:23:58
	System	11 Aug 2020 15:23:58

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 11:10'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 13:40'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:10:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c48f2c13-e3cb-448a-99fe-136e411bb7af' User entered 'Yes (Y)'	System	11 Aug 2020 23:11:20
	System	11 Aug 2020 23:11:20

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:06', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c48f2c13-e3cb-448a-99fe-136e411bb7af' User entered '98.2'	System	11 Aug 2020 23:11:20
	System	11 Aug 2020 23:11:20

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:12', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c48f2c13-e3cb-448a-99fe-136e411bb7af' User entered 'No (N)'	System	11 Aug 2020 23:11:20
	System	11 Aug 2020 23:11:20



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:19', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c48f2c13-e3cb-448a-99fe-136e411bb7af' User entered '11 Aug 2020 19:11'	System	11 Aug 2020 23:11:20
	System	11 Aug 2020 23:11:20

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 14:35'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 2'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:37:35', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2e18241e-43ff-4b9a-aaee-88e5c87e4021' User entered 'Yes (Y)'	System	12 Aug 2020 16:38:07
	System	12 Aug 2020 16:38:07

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:37:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2e18241e-43ff-4b9a-aace-88e5c87e4021' User entered '98.2'	System	12 Aug 2020 16:38:07
	System	12 Aug 2020 16:38:07

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:37:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2e18241e-43ff-4b9a-aace-88e5c87e4021'	System	12 Aug 2020 16:38:07
User entered 'No (N)'	System	12 Aug 2020 16:38:07

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2e18241e-43ff-4b9a-aaee-88e5c87e4021' User entered '12 Aug 2020 12:38'	System	12 Aug 2020 16:38:07
	System	12 Aug 2020 16:38:07



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 3'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:53:40', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '052eeb23-4f9a-4769-915c-6e86a06405a3' User entered 'Yes (Y)'	System	13 Aug 2020 16:53:57
	System	13 Aug 2020 16:53:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:53:48', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '052eeb23-4f9a-4769-915c-6e86a06405a3' User entered '97.8'	System	13 Aug 2020 16:53:57
	System	13 Aug 2020 16:53:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:53:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '052eeb23-4f9a-4769-915c-6e86a06405a3'	System	13 Aug 2020 16:53:57
User entered 'No (N)'	System	13 Aug 2020 16:53:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:53:55', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '052eeb23-4f9a-4769-915c-6e86a06405a3' User entered '13 Aug 2020 12:53'	System	13 Aug 2020 16:53:57
	System	13 Aug 2020 16:53:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 14:56:00



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 4'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a3923491-54da-4d72-af3e-921b488dd87b' User entered 'Yes (Y)'	System	14 Aug 2020 16:20:31
	System	14 Aug 2020 16:20:31

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:24', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a3923491-54da-4d72-af3e-921b488dd87b' User entered '97.1'	System	14 Aug 2020 16:20:31
	System	14 Aug 2020 16:20:31

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:27', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a3923491-54da-4d72-af3e-921b488dd87b' User entered 'No (N)'	System	14 Aug 2020 16:20:31
	System	14 Aug 2020 16:20:31

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:30', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a3923491-54da-4d72-af3e-921b488dd87b' User entered '14 Aug 2020 12:20'	System	14 Aug 2020 16:20:31
	System	14 Aug 2020 16:20:31

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 14:56:00



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 5'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:21:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd9c5d5d8-3b20-4816-97fb-8fbe6f6b877c' User entered 'Yes (Y)'	System	15 Aug 2020 16:21:46
	System	15 Aug 2020 16:21:46

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:21:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd9c5d5d8-3b20-4816-97fb-8fbe6f6b877c' User entered '98.0'	System	15 Aug 2020 16:21:46
	System	15 Aug 2020 16:21:46

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:21:41', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd9c5d5d8-3b20-4816-97fb-8fbe6f6b877c'	System	15 Aug 2020 16:21:46
User entered 'No (N)'	System	15 Aug 2020 16:21:46

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:21:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd9c5d5d8-3b20-4816-97fb-8fbe6f6b877c'	System	15 Aug 2020 16:21:46
User entered '15 Aug 2020 12:21'	System	15 Aug 2020 16:21:46

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 6'	System	11 Aug 2020 14:56:00



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:09:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b943bc10-5e57-4d0d-ae30-db005049d6cd' User entered 'Yes (Y)'	System	16 Aug 2020 16:10:12
	System	16 Aug 2020 16:10:12

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b943bc10-5e57-4d0d-ae30-db005049d6cd' User entered '98.1'	System	16 Aug 2020 16:10:12
	System	16 Aug 2020 16:10:12

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b943bc10-5e57-4d0d-ae30-db005049d6cd'	System	16 Aug 2020 16:10:12
User entered 'No (N)'	System	16 Aug 2020 16:10:12

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b943bc10-5e57-4d0d-ae30-db005049d6cd' User entered '16 Aug 2020 12:10'	System	16 Aug 2020 16:10:12
	System	16 Aug 2020 16:10:12

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 7'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:49:37', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'def34c8e-a873-49a7-a163-dbbec772e43' User entered 'Yes (Y)'	System	17 Aug 2020 18:49:57
	System	17 Aug 2020 18:49:57



US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:49:48', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'def34c8e-a873-49a7-a163-dbbec772e43' User entered '98.1'	System	17 Aug 2020 18:49:57
	System	17 Aug 2020 18:49:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:49:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'def34c8e-a873-49a7-a163-dbbecc772e43'	System	17 Aug 2020 18:49:57
User entered 'No (N)'	System	17 Aug 2020 18:49:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:49:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'def34c8e-a873-49a7-a163-dbbecc772e43' User entered '17 Aug 2020 14:49'	System	17 Aug 2020 18:49:57
	System	17 Aug 2020 18:49:57

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:24:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4e53db57-a9cb-42dc-aed3-baaf85b9c936'	System	11 Aug 2020 15:24:53
User entered 'None (1)'	System	11 Aug 2020 15:24:53

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:24:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4e53db57-a9cb-42dc-aed3-baaf85b9c936'	System	11 Aug 2020 15:24:53
User entered 'No (N)'	System	11 Aug 2020 15:24:53



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:24:33', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4e53db57-a9cb-42dc-aed3-baaf85b9c936' User entered 'No (N)'	System	11 Aug 2020 15:24:53
	System	11 Aug 2020 15:24:53

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:24:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4e53db57-a9cb-42dc-aed3-baaf85b9c936'	System	11 Aug 2020 15:24:53
User entered 'None (1)'	System	11 Aug 2020 15:24:53

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:24:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4e53db57-a9cb-42dc-aed3-baaf85b9c936' User entered '11 Aug 2020 11:24'	System	11 Aug 2020 15:24:53
	System	11 Aug 2020 15:24:53

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 11:10'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 13:40'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:27', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53568364-60af-4e9e-a3e8-c565e0bd98fb' User entered 'None (1)'	System	11 Aug 2020 23:11:46
	System	11 Aug 2020 23:11:46

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:31', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53568364-60af-4e9e-a3e8-c565e0bd98fb' User entered 'No (N)'	System	11 Aug 2020 23:11:46
	System	11 Aug 2020 23:11:46



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:34', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53568364-60af-4e9e-a3e8-c565e0bd98fb' User entered 'No (N)'	System	11 Aug 2020 23:11:46
	System	11 Aug 2020 23:11:46

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:40', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53568364-60af-4e9e-a3e8-c565e0bd98fb' User entered 'None (1)'	System	11 Aug 2020 23:11:46
	System	11 Aug 2020 23:11:46

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53568364-60af-4e9e-a3e8-c565e0bd98fb' User entered '11 Aug 2020 19:11'	System	11 Aug 2020 23:11:46
	System	11 Aug 2020 23:11:46

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 14:35'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 2'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '91f67e9e-54b7-4087-881a-bae517f06291' User entered 'None (1)'	System	12 Aug 2020 16:38:49
	System	12 Aug 2020 16:38:49

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '91f67e9e-54b7-4087-881a-bae517f06291' User entered 'No (N)'	System	12 Aug 2020 16:38:49
	System	12 Aug 2020 16:38:49



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:30', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '91f67e9e-54b7-4087-881a-bae517f06291' User entered 'No (N)'	System	12 Aug 2020 16:38:49
	System	12 Aug 2020 16:38:49

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:45', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '91f67e9e-54b7-4087-881a-bae517f06291' User entered 'None (1)'	System	12 Aug 2020 16:38:49
	System	12 Aug 2020 16:38:49

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:47', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '91f67e9e-54b7-4087-881a-bae517f06291' User entered '12 Aug 2020 12:38'	System	12 Aug 2020 16:38:49
	System	12 Aug 2020 16:38:49

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 3'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:05', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '264f4f1d-662b-4856-bf07-de2dc8be2c9e'	System	13 Aug 2020 16:54:30
User entered 'None (1)'	System	13 Aug 2020 16:54:30

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '264f4f1d-662b-4856-bf07-de2dc8be2c9e'	System	13 Aug 2020 16:54:30
User entered 'No (N)'	System	13 Aug 2020 16:54:30



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '264f4f1d-662b-4856-bf07-de2dc8be2c9e' User entered 'No (N)'	System	13 Aug 2020 16:54:30
	System	13 Aug 2020 16:54:30

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:19', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '264f4f1d-662b-4856-bf07-de2dc8be2c9e' User entered 'None (1)'	System	13 Aug 2020 16:54:30
	System	13 Aug 2020 16:54:30

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '264f4f1d-662b-4856-bf07-de2dc8be2c9e' User entered '13 Aug 2020 12:54'	System	13 Aug 2020 16:54:30
	System	13 Aug 2020 16:54:30

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 4'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:39', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc69e44a-9a57-4132-bd67-a0d06b313d5f' User entered 'None (1)'	System	14 Aug 2020 16:20:58
	System	14 Aug 2020 16:20:58

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc69e44a-9a57-4132-bd67-a0d06b313d5f' User entered 'No (N)'	System	14 Aug 2020 16:20:58
	System	14 Aug 2020 16:20:58



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:48', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc69e44a-9a57-4132-bd67-a0d06b313d5f' User entered 'No (N)'	System	14 Aug 2020 16:20:58
	System	14 Aug 2020 16:20:58

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc69e44a-9a57-4132-bd67-a0d06b313d5f' User entered 'None (1)'	System	14 Aug 2020 16:20:58
	System	14 Aug 2020 16:20:58

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:54', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc69e44a-9a57-4132-bd67-a0d06b313d5f' User entered '14 Aug 2020 12:20'	System	14 Aug 2020 16:20:58
	System	14 Aug 2020 16:20:58

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 5'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:21:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '070db2e4-7e2d-4866-bf74-effeb12f1eb1'	System	15 Aug 2020 16:22:10
User entered 'None (1)'	System	15 Aug 2020 16:22:10

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:21:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '070db2e4-7e2d-4866-bf74-effeb12f1eb1' User entered 'No (N)'	System	15 Aug 2020 16:22:10
	System	15 Aug 2020 16:22:10



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:02', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '070db2e4-7e2d-4866-bf74-effeb12f1eb1' User entered 'No (N)'	System	15 Aug 2020 16:22:10
	System	15 Aug 2020 16:22:10

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:05', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '070db2e4-7e2d-4866-bf74-effeb12f1eb1' User entered 'None (1)'	System	15 Aug 2020 16:22:10
	System	15 Aug 2020 16:22:10

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '070db2e4-7e2d-4866-bf74-effeb12f1eb1' User entered '15 Aug 2020 12:22'	System	15 Aug 2020 16:22:10
	System	15 Aug 2020 16:22:10

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 6'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:15', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '43dd26d6-774f-4342-a1bd-6154cdedf53e'	System	16 Aug 2020 16:10:32
User entered 'None (1)'	System	16 Aug 2020 16:10:32

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '43dd26d6-774f-4342-a1bd-6154cdedf53e' User entered 'No (N)'	System	16 Aug 2020 16:10:32
	System	16 Aug 2020 16:10:32



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:21', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '43dd26d6-774f-4342-a1bd-6154cdedf53e' User entered 'No (N)'	System	16 Aug 2020 16:10:32
	System	16 Aug 2020 16:10:32

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '43dd26d6-774f-4342-a1bd-6154cdedf53e' User entered 'None (1)'	System	16 Aug 2020 16:10:32
	System	16 Aug 2020 16:10:32

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:31', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '43dd26d6-774f-4342-a1bd-6154cdedf53e' User entered '16 Aug 2020 12:10'	System	16 Aug 2020 16:10:32
	System	16 Aug 2020 16:10:32

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 7'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:49:57', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '13910dc6-f735-41f1-98bc-6317a9558ca9' User entered 'None (1)'	System	17 Aug 2020 18:50:14
	System	17 Aug 2020 18:50:14

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '13910dc6-f735-41f1-98bc-6317a9558ca9'	System	17 Aug 2020 18:50:14
User entered 'No (N)'	System	17 Aug 2020 18:50:14



US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:03', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '13910dc6-f735-41f1-98bc-6317a9558ca9' User entered 'No (N)'	System	17 Aug 2020 18:50:14
	System	17 Aug 2020 18:50:14

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '13910dc6-f735-41f1-98bc-6317a9558ca9' User entered 'None (1)'	System	17 Aug 2020 18:50:14
	System	17 Aug 2020 18:50:14

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '13910dc6-f735-41f1-98bc-6317a9558ca9' User entered '17 Aug 2020 14:50'	System	17 Aug 2020 18:50:14
	System	17 Aug 2020 18:50:14

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:05', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'None (0)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'None (0)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'None (0)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'None (0)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'None (0)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:23', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'None (0)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered 'No (N)'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T11:25:31', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2c8d282b-3de7-4d84-af28-7568390b5e94' User entered '11 Aug 2020 11:25'	System	11 Aug 2020 15:25:35
	System	11 Aug 2020 15:25:35

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 11:10'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 13:40'	System	11 Aug 2020 14:56:00



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:49', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'None (0)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'None (0)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:11:57', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'None (0)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:12:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'None (0)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:12:05', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'None (0)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:12:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'None (0)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:12:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered 'No (N)'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19



**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-11T19:12:17', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b871ebb0-0d8d-49a8-bd3e-5c5bca46f468' User entered '11 Aug 2020 19:12'	System	11 Aug 2020 23:12:19
	System	11 Aug 2020 23:12:19

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Aug 2020 14:35'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 2'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:38:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'None (0)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'None (0)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:05', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'None (0)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'None (0)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'None (0)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:17', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'None (0)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:22', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered 'No (N)'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-12T12:39:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9f974815-aafc-4d82-a38d-e5251d1f4df4' User entered '12 Aug 2020 12:39'	System	12 Aug 2020 16:39:31
	System	12 Aug 2020 16:39:31

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 3'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'None (0)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:32', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'None (0)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:35', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'None (0)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'None (0)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'None (0)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:48', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'None (0)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered 'No (N)'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-13T12:54:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9e5e5bb7-1c3b-43f3-ac62-7047a915a2a1' User entered '13 Aug 2020 12:54'	System	13 Aug 2020 16:54:58
	System	13 Aug 2020 16:54:58

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 14:56:00



**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 4'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:20:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'None (0)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:02', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'None (0)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:04', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'None (0)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'None (0)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'None (0)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'None (0)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered 'No (N)'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-14T12:21:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5815761-476d-4089-a6e5-755456c402e1' User entered '14 Aug 2020 12:21'	System	14 Aug 2020 16:21:20
	System	14 Aug 2020 16:21:20

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 5'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'None (0)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'None (0)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:21', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'None (0)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:23', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'None (0)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:26', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'None (0)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'None (0)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:34', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered 'No (N)'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-15T12:22:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '141023f6-61aa-49b6-8982-e6bf87472659' User entered '15 Aug 2020 12:22'	System	15 Aug 2020 16:22:46
	System	15 Aug 2020 16:22:46

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 6'	System	11 Aug 2020 14:56:00



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:35', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'None (0)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'None (0)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:41', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'None (0)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:45', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'None (0)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'None (0)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'None (0)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:10:58', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered 'No (N)'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-16T12:11:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'b72ddfc6-c70d-4aae-93ab-e956b05822ce' User entered '16 Aug 2020 12:11'	System	16 Aug 2020 16:11:03
	System	16 Aug 2020 16:11:03



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 7'	System	11 Aug 2020 14:56:00

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:15', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625' User entered 'None (0)'	System	17 Aug 2020 18:50:37
	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:17', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625'	System	17 Aug 2020 18:50:37
User entered 'None (0)'	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:20', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625' User entered 'None (0)'	System	17 Aug 2020 18:50:37
	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:22', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625' User entered 'None (0)'	System	17 Aug 2020 18:50:37
	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:24', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625' User entered 'None (0)'	System	17 Aug 2020 18:50:37
	System	17 Aug 2020 18:50:37



US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:26', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625'	System	17 Aug 2020 18:50:37
User entered 'None (0)'	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:32', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625' User entered 'No (N)'	System	17 Aug 2020 18:50:37
	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-08-17T14:50:34', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f52dd064-b8f6-47db-8956-8314038c0625'	System	17 Aug 2020 18:50:37
User entered '17 Aug 2020 14:50'	System	17 Aug 2020 18:50:37

US3172028

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 14:56:00

**US3172028**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Aug 2020 14:12:18
	(b) (4)	

US3172028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '18 Aug 2020'	Mariete Rendon (b) (4)	20 Aug 2020 14:12:18
	(b) (4)	

US3172028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	20 Aug 2020 14:12:18
	(b) (4)	



US3172028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Aug 2020 14:12:18
	(b) (4)	

US3172028

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Aug 2020 14:12:03
	(b) (4)	

**US3172028**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	20 Aug 2020 14:12:03

US3172028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	26 Aug 2020 14:32:15
	(b) (4)	

US3172028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '25 Aug 2020'	Mariete Rendon (b) (4)	26 Aug 2020 14:32:15
	(b) (4)	

US3172028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	26 Aug 2020 14:32:15
	(b) (4)	

US3172028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	26 Aug 2020 14:32:15
	(b) (4)	

US3172028

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Mariete Rendon (b) (4)	26 Aug 2020 14:32:19
	(b) (4)	



US3172028

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User entered 'I'	System	26 Aug 2020 14:32:19

US3172028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	01 Sep 2020 16:53:05

US3172028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '01 Sep 2020'	(b) (4)	
	Jessie Downs (b) (4)	01 Sep 2020 16:53:05
	(b) (4)	

US3172028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	01 Sep 2020 16:53:05
	(b) (4)	

US3172028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	01 Sep 2020 16:53:05
	(b) (4)	

US3172028

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	01 Sep 2020 16:53:09

US3172028

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:16
User entered 'I'	System	01 Sep 2020 16:53:09

US3172028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	10 Sep 2020 12:56:21
	(b) (4)	



US3172028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '8 Sep 2020'	(b) (4)	
	Mariete Rendon (b) (4)	10 Sep 2020 12:56:21
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4)	
	Mariete Rendon (b) (4)	10 Sep 2020 12:56:21
	(b) (4)	

**US3172028**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'VISIT2'	System	10 Sep 2020 12:56:21

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '8 Sep 2020'	(b) (4)	
	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '08:40'	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '8 Sep 2020 08:40'	System	10 Sep 2020 12:58:03



US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '36.7' C	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Oral (Oral)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '61'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'bpm'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '14'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'breaths/min'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '155'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03



US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '87'	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '8 Sep 2020'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '11:29'	(b) (4)	
	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '8 Sep 2020 11:29'	System	10 Sep 2020 12:58:03



US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '36.8' C	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Oral (Oral)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '69'	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'bpm'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '14'	Mariete Rendon (b) (4)	10 Sep 2020 12:58:03
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'breaths/min'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:26:29
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:51:04
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Abnormal, NCS. Part of baseline medical history. subject stressed out due to work. subject asymptomatic' (Site from System).	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:00:41
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Sep 2020 12:58:03
User entered '170'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03



US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '81'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	10 Sep 2020 12:58:03

US3172028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	10 Sep 2020 13:01:01
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '8 Sep 2020'	Mariete Rendon (b) (4)	10 Sep 2020 13:01:01
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	08 Sep 2020 14:55:39
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	08 Sep 2020 14:55:39
	(b) (4)	



US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '08 Sep 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '10:49'	(b) (4) Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '08 Sep 2020 10:49'	System	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4)	
	Jessie Downs (b) (4)	08 Sep 2020 14:55:39
	(b) (4)	

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'ONCE'	System	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:55:39

US3172028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:25



US3172028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '8 Sep 2020'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:25

US3172028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '10:06'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:25

US3172028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '8 Sep 2020 10:06'	System	10 Sep 2020 13:01:25

US3172028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '8 Sep 2020'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:35

**US3172028**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:35

US3172028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:35

US3172028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '10:04'	(b) (4)	
	Mariete Rendon (b) (4)	10 Sep 2020 13:01:35
	(b) (4)	

**US3172028**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '8 Sep 2020 10:04'	System	10 Sep 2020 13:01:35



**US3172028**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:35

US3172028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 13:01:35

US3172028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	10 Sep 2020 13:01:35
	(b) (4)	

**US3172028**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered empty.	System	10 Sep 2020 13:01:35

US3172028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	10 Sep 2020 13:01:39
	(b) (4)	

**US3172028**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '1'	System	10 Sep 2020 13:01:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2f0df8f7-ce0e-4606-b5c3-acb291850625' User entered 'Yes (Y)'	System	08 Sep 2020 15:20:37
	System	08 Sep 2020 15:20:37



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:24', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2f0df8f7-ce0e-4606-b5c3-acb291850625' User entered '98.2'	System	08 Sep 2020 15:20:37
	System	08 Sep 2020 15:20:37

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2f0df8f7-ce0e-4606-b5c3-acb291850625'	System	08 Sep 2020 15:20:37
User entered 'No (N)'	System	08 Sep 2020 15:20:37

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:33', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2f0df8f7-ce0e-4606-b5c3-acb291850625' User entered '08 Sep 2020 11:20'	System	08 Sep 2020 15:20:37
	System	08 Sep 2020 15:20:37

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 11:09'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 13:39'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '0220e769-6def-4fdd-a061-1ab29a54174a' User entered 'Yes (Y)'	System	09 Sep 2020 02:40:31
	System	09 Sep 2020 02:40:31

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '0220e769-6def-4fdd-a061-1ab29a54174a' User entered '96.6'	System	09 Sep 2020 02:40:31
	System	09 Sep 2020 02:40:31



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '0220e769-6def-4fdd-a061-1ab29a54174a' User entered 'No (N)'	System	09 Sep 2020 02:40:31
	System	09 Sep 2020 02:40:31

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '0220e769-6def-4fdd-a061-1ab29a54174a' User entered '08 Sep 2020 22:40'	System	09 Sep 2020 02:40:31
	System	09 Sep 2020 02:40:31

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 14:34'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 2'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fb33a621-b444-4a3e-9a41-ccbfae6c043a' User entered 'Yes (Y)'	System	09 Sep 2020 16:32:38
	System	09 Sep 2020 16:32:38

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fb33a621-b444-4a3e-9a41-ccbfae6c043a' User entered '97.8'	System	09 Sep 2020 16:32:38
	System	09 Sep 2020 16:32:38

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fb33a621-b444-4a3e-9a41-ccbfae6c043a' User entered 'No (N)'	System	09 Sep 2020 16:32:38
	System	09 Sep 2020 16:32:38



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:34', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fb33a621-b444-4a3e-9a41-ccbfae6c043a' User entered '09 Sep 2020 12:32'	System	09 Sep 2020 16:32:38
	System	09 Sep 2020 16:32:38

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 3'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:02', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cf73aac9-715d-4670-8f81-e76b347b9af9' User entered 'Yes (Y)'	System	11 Sep 2020 10:25:24
	System	11 Sep 2020 10:25:24

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:15', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cf73aac9-715d-4670-8f81-e76b347b9af9' User entered '97.0'	System	11 Sep 2020 10:25:24
	System	11 Sep 2020 10:25:24

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cf73aac9-715d-4670-8f81-e76b347b9af9'	System	11 Sep 2020 10:25:24
User entered 'No (N)'	System	11 Sep 2020 10:25:24

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:21', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cf73aac9-715d-4670-8f81-e76b347b9af9'	System	11 Sep 2020 10:25:24
User entered '11 Sep 2020 06:25'	System	11 Sep 2020 10:25:24



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 4'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:40:43', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1103d510-484f-49da-b34e-e5b8a0681865' User entered 'Yes (Y)'	System	11 Sep 2020 20:41:05
	System	11 Sep 2020 20:41:05

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:40:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1103d510-484f-49da-b34e-e5b8a0681865' User entered '97.6'	System	11 Sep 2020 20:41:05
	System	11 Sep 2020 20:41:05

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:40:55', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1103d510-484f-49da-b34e-e5b8a0681865'	System	11 Sep 2020 20:41:05
User entered 'No (N)'	System	11 Sep 2020 20:41:05

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1103d510-484f-49da-b34e-e5b8a0681865' User entered '11 Sep 2020 16:41'	System	11 Sep 2020 20:41:05
	System	11 Sep 2020 20:41:05

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:55:39



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 5'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a2f48fec-54d6-4111-94cf-4161a9e87cf0' User entered 'Yes (Y)'	System	12 Sep 2020 16:33:30
	System	12 Sep 2020 16:33:30

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:21', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a2f48fec-54d6-4111-94cf-4161a9e87cf0' User entered '97.3'	System	12 Sep 2020 16:33:30
	System	12 Sep 2020 16:33:30

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a2f48fec-54d6-4111-94cf-4161a9e87cf0' User entered 'No (N)'	System	12 Sep 2020 16:33:30
	System	12 Sep 2020 16:33:30

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a2f48fec-54d6-4111-94cf-4161a9e87cf0' User entered '12 Sep 2020 12:33'	System	12 Sep 2020 16:33:30
	System	12 Sep 2020 16:33:30

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:55:39



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 6'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:11:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bc775495-e453-4cff-b051-7cf2efebcd18' User entered 'Yes (Y)'	System	13 Sep 2020 16:12:12
	System	13 Sep 2020 16:12:12

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:11:57', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bc775495-e453-4cff-b051-7cf2efebcd18' User entered '97.2'	System	13 Sep 2020 16:12:12
	System	13 Sep 2020 16:12:12

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bc775495-e453-4cff-b051-7cf2efebcd18'	System	13 Sep 2020 16:12:12
User entered 'No (N)'	System	13 Sep 2020 16:12:12

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:03', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bc775495-e453-4cff-b051-7cf2efebcd18' User entered '13 Sep 2020 12:12'	System	13 Sep 2020 16:12:12
	System	13 Sep 2020 16:12:12

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 7'	System	08 Sep 2020 14:55:39



US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e10c87e5-1713-4a7e-930e-8f4b9b3850ca' User entered 'Yes (Y)'	System	14 Sep 2020 16:12:47
	System	14 Sep 2020 16:12:47

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:20', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e10c87e5-1713-4a7e-930e-8f4b9b3850ca' User entered '98.1'	System	14 Sep 2020 16:12:47
	System	14 Sep 2020 16:12:47

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:23', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e10c87e5-1713-4a7e-930e-8f4b9b3850ca' User entered 'No (N)'	System	14 Sep 2020 16:12:47
	System	14 Sep 2020 16:12:47

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:26', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e10c87e5-1713-4a7e-930e-8f4b9b3850ca' User entered '14 Sep 2020 12:11'	System	14 Sep 2020 16:12:47
	System	14 Sep 2020 16:12:47

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:37', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e8462749-5802-49cc-843b-c0661fc546db' User entered 'None (1)'	System	08 Sep 2020 15:21:03
	System	08 Sep 2020 15:21:03



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e8462749-5802-49cc-843b-c0661fc546db' User entered 'No (N)'	System	08 Sep 2020 15:21:03
	System	08 Sep 2020 15:21:03

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:54', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e8462749-5802-49cc-843b-c0661fc546db' User entered 'No (N)'	System	08 Sep 2020 15:21:03
	System	08 Sep 2020 15:21:03

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:20:57', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e8462749-5802-49cc-843b-c0661fc546db' User entered 'None (1)'	System	08 Sep 2020 15:21:03
	System	08 Sep 2020 15:21:03

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'e8462749-5802-49cc-843b-c0661fc546db' User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:21:03
	System	08 Sep 2020 15:21:03

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 11:09'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 13:39'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:40', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3cb8b86f-7203-470a-b4f6-f02bfa677d99'	System	09 Sep 2020 02:41:04
User entered 'None (1)'	System	09 Sep 2020 02:41:04



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:43', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3cb8b86f-7203-470a-b4f6-f02bfa677d99'	System	09 Sep 2020 02:41:04
User entered 'No (N)'	System	09 Sep 2020 02:41:04

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:47', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3cb8b86f-7203-470a-b4f6-f02bfa677d99'	System	09 Sep 2020 02:41:04
User entered 'No (N)'	System	09 Sep 2020 02:41:04

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3cb8b86f-7203-470a-b4f6-f02bfa677d99'	System	09 Sep 2020 02:41:04
User entered 'None (1)'	System	09 Sep 2020 02:41:04

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:40:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3cb8b86f-7203-470a-b4f6-f02bfa677d99'	System	09 Sep 2020 02:41:04
User entered '08 Sep 2020 22:40'	System	09 Sep 2020 02:41:04

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 14:34'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 2'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ad4b9e38-9b73-4f32-bd05-2d23d371022e'	System	09 Sep 2020 16:32:54
User entered 'None (1)'	System	09 Sep 2020 16:32:54



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:41', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ad4b9e38-9b73-4f32-bd05-2d23d371022e' User entered 'No (N)'	System	09 Sep 2020 16:32:54
	System	09 Sep 2020 16:32:54

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:43', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ad4b9e38-9b73-4f32-bd05-2d23d371022e' User entered 'No (N)'	System	09 Sep 2020 16:32:54
	System	09 Sep 2020 16:32:54

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:47', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ad4b9e38-9b73-4f32-bd05-2d23d371022e'	System	09 Sep 2020 16:32:54
User entered 'None (1)'	System	09 Sep 2020 16:32:54

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ad4b9e38-9b73-4f32-bd05-2d23d371022e' User entered '09 Sep 2020 12:32'	System	09 Sep 2020 16:32:54
	System	09 Sep 2020 16:32:54

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 3'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '744a19f2-41f8-4ee1-9909-19c2778d37e1' User entered 'None (1)'	System	11 Sep 2020 10:25:41
	System	11 Sep 2020 10:25:41



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '744a19f2-41f8-4ee1-9909-19c2778d37e1' User entered 'No (N)'	System	11 Sep 2020 10:25:41
	System	11 Sep 2020 10:25:41

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:32', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '744a19f2-41f8-4ee1-9909-19c2778d37e1' User entered 'No (N)'	System	11 Sep 2020 10:25:41
	System	11 Sep 2020 10:25:41

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:36', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '744a19f2-41f8-4ee1-9909-19c2778d37e1' User entered 'None (1)'	System	11 Sep 2020 10:25:41
	System	11 Sep 2020 10:25:41

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '744a19f2-41f8-4ee1-9909-19c2778d37e1' User entered '11 Sep 2020 06:25'	System	11 Sep 2020 10:25:41
	System	11 Sep 2020 10:25:41

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 4'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:04', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5bdcff1-936e-4a66-b02b-d2f6b2e03757'	System	11 Sep 2020 20:41:19
User entered 'None (1)'	System	11 Sep 2020 20:41:19



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:08', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5bdcff1-936e-4a66-b02b-d2f6b2e03757'	System	11 Sep 2020 20:41:19
User entered 'No (N)'	System	11 Sep 2020 20:41:19

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5bdcff1-936e-4a66-b02b-d2f6b2e03757'	System	11 Sep 2020 20:41:19
User entered 'No (N)'	System	11 Sep 2020 20:41:19

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5bdcff1-936e-4a66-b02b-d2f6b2e03757'	System	11 Sep 2020 20:41:19
User entered 'None (1)'	System	11 Sep 2020 20:41:19

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'd5bdcff1-936e-4a66-b02b-d2f6b2e03757'	System	11 Sep 2020 20:41:19
User entered '11 Sep 2020 16:41'	System	11 Sep 2020 20:41:19

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 5'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:34', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ca5ce254-2912-4914-bdcd-9cd68cc953dc' User entered 'None (1)'	System	12 Sep 2020 16:33:49
	System	12 Sep 2020 16:33:49



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ca5ce254-2912-4914-bdcd-9cd68cc953dc' User entered 'No (N)'	System	12 Sep 2020 16:33:49
	System	12 Sep 2020 16:33:49

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:41', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ca5ce254-2912-4914-bdcd-9cd68cc953dc' User entered 'No (N)'	System	12 Sep 2020 16:33:49
	System	12 Sep 2020 16:33:49

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ca5ce254-2912-4914-bdcd-9cd68cc953dc' User entered 'None (1)'	System	12 Sep 2020 16:33:49
	System	12 Sep 2020 16:33:49

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:46', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ca5ce254-2912-4914-bdcd-9cd68cc953dc' User entered '12 Sep 2020 12:33'	System	12 Sep 2020 16:33:49
	System	12 Sep 2020 16:33:49

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 6'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3ae4c10c-5e39-46f1-943f-d7edb5626278'	System	13 Sep 2020 16:12:34
User entered 'None (1)'	System	13 Sep 2020 16:12:34



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3ae4c10c-5e39-46f1-943f-d7edb5626278' User entered 'No (N)'	System	13 Sep 2020 16:12:34
	System	13 Sep 2020 16:12:34

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:21', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3ae4c10c-5e39-46f1-943f-d7edb5626278' User entered 'No (N)'	System	13 Sep 2020 16:12:34
	System	13 Sep 2020 16:12:34

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:29', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3ae4c10c-5e39-46f1-943f-d7edb5626278'	System	13 Sep 2020 16:12:34
User entered 'None (1)'	System	13 Sep 2020 16:12:34

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:31', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '3ae4c10c-5e39-46f1-943f-d7edb5626278' User entered '13 Sep 2020 12:12'	System	13 Sep 2020 16:12:34
	System	13 Sep 2020 16:12:34

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 7'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:32', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '058d9edb-82e2-4097-bf02-23c2e6d6c6d7'	System	14 Sep 2020 16:12:56
User entered 'None (1)'	System	14 Sep 2020 16:12:56



US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:36', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '058d9edb-82e2-4097-bf02-23c2e6d6c6d7' User entered 'No (N)'	System	14 Sep 2020 16:12:56
	System	14 Sep 2020 16:12:56

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:39', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '058d9edb-82e2-4097-bf02-23c2e6d6c6d7' User entered 'No (N)'	System	14 Sep 2020 16:12:56
	System	14 Sep 2020 16:12:56

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '058d9edb-82e2-4097-bf02-23c2e6d6c6d7'	System	14 Sep 2020 16:12:56
User entered 'None (1)'	System	14 Sep 2020 16:12:56

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:49', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '058d9edb-82e2-4097-bf02-23c2e6d6c6d7'	System	14 Sep 2020 16:12:56
User entered '14 Sep 2020 12:11'	System	14 Sep 2020 16:12:56

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:08', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'None (0)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'None (0)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'None (0)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:15', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'None (0)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'None (0)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:20', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'None (0)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:24', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered 'No (N)'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T11:21:33', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '56f53aab-51c8-4454-be1f-9f4382f38389' User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:21:36
	System	08 Sep 2020 15:21:36

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 11:09'	System	08 Sep 2020 14:55:39



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 13:39'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:04', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'None (0)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'None (0)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'None (0)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'None (0)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:17', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'None (0)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:20', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'None (0)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:24', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered 'No (N)'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-08T22:41:40', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'bdcdfca5-275a-4145-a638-a9caa59de7ed' User entered '08 Sep 2020 22:41'	System	09 Sep 2020 02:41:43
	System	09 Sep 2020 02:41:43

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '08 Sep 2020 14:34'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 2'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'None (0)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:32:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'None (0)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:33:02', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'None (0)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:33:06', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'None (0)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:33:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'None (0)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:33:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'None (0)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:33:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered 'No (N)'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-09T12:33:16', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c8a07a74-2224-475f-a6b4-6c62dd3d39be' User entered '09 Sep 2020 12:33'	System	09 Sep 2020 16:33:19
	System	09 Sep 2020 16:33:19

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 3'	System	08 Sep 2020 14:55:39



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'None (0)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'None (0)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:47', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'None (0)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:49', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'None (0)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'None (0)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:54', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'None (0)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:25:57', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered 'No (N)'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T06:26:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cb9a6a1b-0664-40de-b795-a9adb708e0ee' User entered '11 Sep 2020 06:26'	System	11 Sep 2020 10:26:04
	System	11 Sep 2020 10:26:04



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 4'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:20', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'None (0)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:22', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'None (0)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'None (0)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'None (0)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:31', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'None (0)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:34', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'None (0)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered 'No (N)'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-11T16:41:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'aa504d5d-66a6-4364-a904-c9f77f3e22d1' User entered '11 Sep 2020 16:41'	System	11 Sep 2020 20:41:48
	System	11 Sep 2020 20:41:48

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 5'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:51', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'None (0)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:54', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'None (0)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'None (0)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:33:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'None (0)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:34:02', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'None (0)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:34:05', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'None (0)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:34:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered 'No (N)'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-12T12:34:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6b50438e-866b-45d8-a42d-d12783a8dc7d' User entered '12 Sep 2020 12:34'	System	12 Sep 2020 16:34:17
	System	12 Sep 2020 16:34:17

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:55:39



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 6'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:35', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'None (0)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:37', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'None (0)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:39', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'None (0)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:41', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'None (0)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'None (0)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:46', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'None (0)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:12:50', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered 'No (N)'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02



**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-13T12:13:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fdf4578c-bfde-4703-88ba-1c2b68e6406f' User entered '13 Sep 2020 12:13'	System	13 Sep 2020 16:13:02
	System	13 Sep 2020 16:13:02

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	08 Sep 2020 14:55:39
User entered 'Day 7'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'None (0)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'None (0)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:11:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'None (0)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:12:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'None (0)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01



US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:12:04', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'None (0)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:12:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'None (0)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:12:11', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered 'No (N)'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

**US3172028**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:33:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-09-14T12:12:13', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '53ee2bc1-d04d-41ef-b5d4-9c5e2c1a0e6b' User entered '14 Sep 2020 12:12'	System	14 Sep 2020 16:13:01
	System	14 Sep 2020 16:13:01

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:55:39

US3172028

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:55:39

US3172028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	23 Sep 2020 17:55:55

US3172028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '15 Sep 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	23 Sep 2020 17:55:55



US3172028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	23 Sep 2020 17:55:55
	(b) (4)	

US3172028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	23 Sep 2020 17:55:55
	(b) (4)	

US3172028

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	23 Sep 2020 17:56:00

**US3172028**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	23 Sep 2020 17:56:00

US3172028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	23 Sep 2020 17:56:14

US3172028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '22 Sep 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	23 Sep 2020 17:56:14

US3172028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	23 Sep 2020 17:56:14
	(b) (4)	

US3172028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Sep 2020 17:56:14
	(b) (4)	



US3172028

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	23 Sep 2020 17:56:18
	(b) (4)	

**US3172028**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	23 Sep 2020 17:56:18

US3172028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 17:59:24
	(b) (4)	

US3172028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '29 Sep 2020'	(b) (4)	
	Mariete Rendon (b) (4)	30 Sep 2020 17:59:24
	(b) (4)	

US3172028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	30 Sep 2020 17:59:24
	(b) (4)	

US3172028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 17:59:24
	(b) (4)	

US3172028

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Mariete Rendon (b) (4)	30 Sep 2020 17:59:27
	(b) (4)	

**US3172028**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	30 Sep 2020 17:59:27



US3172028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:20:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '06 Oct 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:20:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4)	
	Jessie Downs (b) (4)	06 Oct 2020 19:20:51
	(b) (4)	

**US3172028**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'VISIT3'	System	06 Oct 2020 19:20:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '06 Oct 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '11:29'	(b) (4)	
	Jessie Downs (b) (4)	06 Oct 2020 19:23:51
	(b) (4)	

**US3172028**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:33:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '06 Oct 2020 11:29'	System	06 Oct 2020 19:23:51



US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '36.9' C	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Oral (Oral)'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '61'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'bpm'	System	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '13'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'breaths/min'	System	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '132'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51



US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered '79'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'mmHg'	System	06 Oct 2020 19:23:51

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41

US3172028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41

US3172028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	06 Oct 2020 19:21:05
	(b) (4)	

US3172028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:21:05

US3172028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:06



US3172028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '06 Oct 2020'	(b) (4)	
	Jessie Downs (b) (4)	06 Oct 2020 19:23:06
	(b) (4)	

US3172028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
User entered '11:51'	(b) (4)	
	Jessie Downs (b) (4)	06 Oct 2020 19:23:06
	(b) (4)	

**US3172028**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:33:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered '06 Oct 2020 11:51'	System	06 Oct 2020 19:23:06

US3172028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	06 Oct 2020 19:23:11

**US3172028**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	06 Oct 2020 19:23:11

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 64'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-11T06:37:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '656eff9d-48f9-4980-a793-d1d319101d0c'	System	11 Oct 2020 10:38:27
User entered 'No (N)'	System	11 Oct 2020 10:38:27

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-11T06:37:45', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '656eff9d-48f9-4980-a793-d1d319101d0c'	System	11 Oct 2020 10:38:27
User entered 'No (N)'	System	11 Oct 2020 10:38:27



**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-11T06:37:52', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '656eff9d-48f9-4980-a793-d1d319101d0c' User entered '11 Oct 2020 06:37:52'	System	11 Oct 2020 10:38:27
	System	11 Oct 2020 10:38:27

**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 71'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-18T00:03:50', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '10ed1758-0717-4dda-b82f-e2726bc49ae2'	System	18 Oct 2020 04:04:09
User entered 'No (N)'	System	18 Oct 2020 04:04:09

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-18T00:03:55', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '10ed1758-0717-4dda-b82f-e2726bc49ae2'	System	18 Oct 2020 04:04:09
User entered 'No (N)'	System	18 Oct 2020 04:04:09

**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-18T00:04:04', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '10ed1758-0717-4dda-b82f-e2726bc49ae2' User entered '18 Oct 2020 00:04:04'	System	18 Oct 2020 04:04:09
	System	18 Oct 2020 04:04:09

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 14:56:00



US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 14:56:00

**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 78'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-25T07:18:33', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'af365e57-2b76-4fcc-b980-a5e5961bc7af' User entered 'No (N)'	System	25 Oct 2020 11:18:50
	System	25 Oct 2020 11:18:50

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-25T07:18:44', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'af365e57-2b76-4fcc-b980-a5e5961bc7af'	System	25 Oct 2020 11:18:50
User entered 'No (N)'	System	25 Oct 2020 11:18:50

**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-10-25T07:18:48', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'af365e57-2b76-4fcc-b980-a5e5961bc7af' User entered '25 Oct 2020 07:18:48'	System	25 Oct 2020 11:18:50
	System	25 Oct 2020 11:18:50

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 92'	System	11 Aug 2020 14:56:00



US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-08T06:59:50', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '85976b38-dceb-441c-8ec1-a35728450ef0'	System	08 Nov 2020 12:00:07
User entered 'No (N)'	System	08 Nov 2020 12:00:07

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-08T06:59:54', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '85976b38-dceb-441c-8ec1-a35728450ef0'	System	08 Nov 2020 12:00:07
User entered 'No (N)'	System	08 Nov 2020 12:00:07

**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-08T07:00:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '85976b38-dceb-441c-8ec1-a35728450ef0' User entered '08 Nov 2020 07:00:01'	System	08 Nov 2020 12:00:07
	System	08 Nov 2020 12:00:07

**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered 'Day 99'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-15T00:01:39', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cd603daa-565e-43a4-acc1-ee80085d2f8d' User entered 'No (N)'	System	15 Nov 2020 05:02:01
	System	15 Nov 2020 05:02:01

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-15T00:01:55', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cd603daa-565e-43a4-acc1-ee80085d2f8d' User entered 'No (N)'	System	15 Nov 2020 05:02:01
	System	15 Nov 2020 05:02:01



**US3172028**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-15T00:01:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cd603daa-565e-43a4-acc1-ee80085d2f8d' User entered '15 Nov 2020 00:01:59'	System	15 Nov 2020 05:02:01
	System	15 Nov 2020 05:02:01

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 14:56:00

US3172028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:21
Data entry locked.	System	11 Aug 2020 14:56:00
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 14:56:00

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-22T00:08:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9990ada9-f935-402e-b528-301cc3aac96e' User entered 'No (N)'	System	22 Nov 2020 05:13:47
	System	22 Nov 2020 05:13:47

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-22T00:08:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9990ada9-f935-402e-b528-301cc3aac96e'	System	22 Nov 2020 05:13:47
User entered 'No (N)'	System	22 Nov 2020 05:13:47

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-22T00:08:26', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '9990ada9-f935-402e-b528-301cc3aac96e' User entered '22 Nov 2020 00:08:26'	System	22 Nov 2020 05:13:47
	System	22 Nov 2020 05:13:47

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-26T07:17:53', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '33fe52b2-9618-4501-ae35-8b90adf10fca' User entered 'No (N)'	System	26 Nov 2020 12:18:05
	System	26 Nov 2020 12:18:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-26T07:17:58', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '33fe52b2-9618-4501-ae35-8b90adf10fca' User entered 'No (N)'	System	26 Nov 2020 12:18:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-11-26T07:18:02', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '33fe52b2-9618-4501-ae35-8b90adf10fca' User entered '26 Nov 2020 07:18:02'	System	26 Nov 2020 12:18:05
	System	26 Nov 2020 12:18:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-03T07:57:38', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6cb165d8-902f-4c8c-bfc0-186cdf5476d' User entered 'No (N)'	System	03 Dec 2020 12:57:52
	System	03 Dec 2020 12:57:52

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-03T07:57:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6cb165d8-902f-4c8c-bfc0-186cdf5476d' User entered 'No (N)'	System	03 Dec 2020 12:57:52
	System	03 Dec 2020 12:57:52

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-03T07:57:46', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6cb165d8-902f-4c8c-bfc0-186cdf5476d' User entered '03 Dec 2020 07:57:46'	System	03 Dec 2020 12:57:52
	System	03 Dec 2020 12:57:52

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-10T04:07:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cecd8c2b-edc9-4d78-a11c-b206d1b735ee' User entered 'No (N)'	System	10 Dec 2020 09:07:26
	System	10 Dec 2020 09:07:26

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-10T04:07:20', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cecd8c2b-edc9-4d78-a11c-b206d1b735ee' User entered 'No (N)'	System	10 Dec 2020 09:07:26



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-10T04:07:22', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cecd8c2b-edc9-4d78-a11c-b206d1b735ee' User entered '10 Dec 2020 04:07:22'	System	10 Dec 2020 09:07:26
	System	10 Dec 2020 09:07:26

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-17T01:04:25', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6048f5b1-e008-4172-ab67-d8644516d5be' User entered 'No (N)'	System	17 Dec 2020 06:04:36
	System	17 Dec 2020 06:04:36

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-17T01:04:28', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6048f5b1-e008-4172-ab67-d8644516d5be' User entered 'No (N)'	System	17 Dec 2020 06:04:36
	System	17 Dec 2020 06:04:36

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-17T01:04:32', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6048f5b1-e008-4172-ab67-d8644516d5be' User entered '17 Dec 2020 01:04:32'	System	17 Dec 2020 06:04:36
	System	17 Dec 2020 06:04:36

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-24T07:20:22', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '792c1c6b-1d75-4ad1-a8a2-ec7a24d2d082'	System	24 Dec 2020 12:20:29
User entered 'No (N)'	System	24 Dec 2020 12:20:29

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-24T07:20:24', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '792c1c6b-1d75-4ad1-a8a2-ec7a24d2d082' User entered 'No (N)'	System	24 Dec 2020 12:20:29
	System	24 Dec 2020 12:20:29

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-24T07:20:27', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '792c1c6b-1d75-4ad1-a8a2-ec7a24d2d082' User entered '24 Dec 2020 07:20:27'	System	24 Dec 2020 12:20:29
	System	24 Dec 2020 12:20:29

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-31T04:33:04', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6c6ab958-24c6-4ee3-a38d-9130f10bf352' User entered 'No (N)'	System	31 Dec 2020 09:33:11
	System	31 Dec 2020 09:33:11

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-31T04:33:06', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6c6ab958-24c6-4ee3-a38d-9130f10bf352'	System	31 Dec 2020 09:33:11
User entered 'No (N)'	System	31 Dec 2020 09:33:11

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2020-12-31T04:33:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '6c6ab958-24c6-4ee3-a38d-9130f10bf352' User entered '31 Dec 2020 04:33:09'	System	31 Dec 2020 09:33:11
	System	31 Dec 2020 09:33:11

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-07T23:03:19', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'df57c23b-285d-40f7-80a3-ac051c740189'	System	08 Jan 2021 04:03:32
User entered 'No (N)'	System	08 Jan 2021 04:03:32

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-07T23:03:23', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'df57c23b-285d-40f7-80a3-ac051c740189'	System	08 Jan 2021 04:03:32
User entered 'No (N)'	System	08 Jan 2021 04:03:32



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-07T23:03:26', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'df57c23b-285d-40f7-80a3-ac051c740189' User entered '07 Jan 2021 23:03:26'	System	08 Jan 2021 04:03:32
	System	08 Jan 2021 04:03:32

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-14T00:01:59', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4ca1ef76-1e86-42d1-bce5-74bfc5a6cd6a' User entered 'No (N)'	System	14 Jan 2021 05:02:35
	System	14 Jan 2021 05:02:35

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-14T00:02:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4ca1ef76-1e86-42d1-bce5-74bfc5a6cd6a'	System	14 Jan 2021 05:02:35
User entered 'No (N)'	System	14 Jan 2021 05:02:35

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-14T00:02:07', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '4ca1ef76-1e86-42d1-bce5-74bfc5a6cd6a' User entered '14 Jan 2021 00:02:07'	System	14 Jan 2021 05:02:35
	System	14 Jan 2021 05:02:35

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-21T06:51:10', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c728ea45-b3ee-49f8-be5c-903ef2055a4a' User entered 'No (N)'	System	21 Jan 2021 11:51:42

US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-21T06:51:18', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c728ea45-b3ee-49f8-be5c-903ef2055a4a' User entered 'Yes (Y)'	System	21 Jan 2021 11:51:42
	System	21 Jan 2021 11:51:42

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Please 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-21T06:51:27', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c728ea45-b3ee-49f8-be5c-903ef2055a4a'	System	21 Jan 2021 11:51:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Jan 2021 11:51:42

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-21T06:51:31', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'c728ea45-b3ee-49f8-be5c-903ef2055a4a' User entered '21 Jan 2021 06:51:31'	System	21 Jan 2021 11:51:42

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-28T05:59:01', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f6ed3055-5b27-4192-9a58-cfa23056c6fe' User entered 'No (N)'	System	28 Jan 2021 10:59:11
	System	28 Jan 2021 10:59:11

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-28T05:59:03', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f6ed3055-5b27-4192-9a58-cfa23056c6fe' User entered 'No (N)'	System	28 Jan 2021 10:59:11

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-01-28T05:59:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f6ed3055-5b27-4192-9a58-cfa23056c6fe' User entered '28 Jan 2021 05:59:09'	System	28 Jan 2021 10:59:11
	System	28 Jan 2021 10:59:11

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-04T00:01:42', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f07df7b5-7301-4a9f-9842-047cd02ef6a4' User entered 'No (N)'	System	04 Feb 2021 18:44:03
	System	04 Feb 2021 18:44:03



US3172028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:24

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-04T00:01:46', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f07df7b5-7301-4a9f-9842-047cd02ef6a4'	System	04 Feb 2021 18:44:03
User entered 'No (N)'	System	04 Feb 2021 18:44:03

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-04T00:01:50', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f07df7b5-7301-4a9f-9842-047cd02ef6a4' User entered '04 Feb 2021 00:01:50'	System	04 Feb 2021 18:44:03
	System	04 Feb 2021 18:44:03

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-11T07:00:41', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1107a6b7-bba9-4b5c-bd72-e1bae4f87c64' User entered 'No (N)'	System	14 Feb 2021 15:11:18
	System	14 Feb 2021 15:11:18

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-11T07:00:45', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1107a6b7-bba9-4b5c-bd72-e1bae4f87c64' User entered 'No (N)'	System	14 Feb 2021 15:11:18
	System	14 Feb 2021 15:11:18

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-11T07:00:56', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '1107a6b7-bba9-4b5c-bd72-e1bae4f87c64' User entered '11 Feb 2021 07:00:56'	System	14 Feb 2021 15:11:18
	System	14 Feb 2021 15:11:18



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-18T05:14:09', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a77ab57b-bcdd-4069-a230-04d03979b663'	System	18 Feb 2021 10:14:19
User entered 'No (N)'	System	18 Feb 2021 10:14:19

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-18T05:14:12', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a77ab57b-bcdd-4069-a230-04d03979b663'	System	18 Feb 2021 10:14:19
User entered 'No (N)'	System	18 Feb 2021 10:14:19

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-18T05:14:14', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'a77ab57b-bcdd-4069-a230-04d03979b663'	System	18 Feb 2021 10:14:19
User entered '18 Feb 2021 05:14:14'	System	18 Feb 2021 10:14:19

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-25T06:56:24-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2b20e6f0-ceac-4558-8b77-a7ba76fae479'	System	25 Feb 2021 14:23:47
User entered 'No (N)'	System	25 Feb 2021 14:23:47

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-25T06:56:28-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2b20e6f0-ceac-4558-8b77-a7ba76fae479'	System	25 Feb 2021 14:23:47
User entered 'No (N)'	System	25 Feb 2021 14:23:47

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-02-25T06:56:31-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '2b20e6f0-ceac-4558-8b77-a7ba76fae479' User entered '25 Feb 2021 11:56:31'	System	25 Feb 2021 14:23:47
	System	25 Feb 2021 14:23:47

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-04T06:05:27-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ea4d8cf8-8290-48cd-9874-7168e904a2f9' User entered 'No (N)'	System	04 Mar 2021 11:05:38
	System	04 Mar 2021 11:05:38



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-04T06:05:31-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ea4d8cf8-8290-48cd-9874-7168e904a2f9'	System	04 Mar 2021 11:05:38
User entered 'No (N)'	System	04 Mar 2021 11:05:38

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-04T06:05:34-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ea4d8cf8-8290-48cd-9874-7168e904a2f9' User entered '04 Mar 2021 06:05:34'	System	04 Mar 2021 11:05:38
	System	04 Mar 2021 11:05:38

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-11T05:56:26-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '629bd7b1-b8ee-4b65-8e27-1b6461ade7e0'	System	11 Mar 2021 10:56:35
User entered 'No (N)'	System	11 Mar 2021 10:56:35

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-11T05:56:29-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '629bd7b1-b8ee-4b65-8e27-1b6461ade7e0'	System	11 Mar 2021 10:56:35
User entered 'No (N)'	System	11 Mar 2021 10:56:35

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-11T05:56:32-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '629bd7b1-b8ee-4b65-8e27-1b6461ade7e0' User entered '11 Mar 2021 05:56:32'	System	11 Mar 2021 10:56:35
	System	11 Mar 2021 10:56:35



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-18T06:25:29-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fe8572a3-e937-48af-8264-e156ad9c63e2'	System	18 Mar 2021 10:25:41
User entered 'No (N)'	System	18 Mar 2021 10:25:41

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-18T06:25:31-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fe8572a3-e937-48af-8264-e156ad9c63e2'	System	18 Mar 2021 10:25:41
User entered 'No (N)'	System	18 Mar 2021 10:25:41

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-18T06:25:35-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'fe8572a3-e937-48af-8264-e156ad9c63e2'	System	18 Mar 2021 10:25:41
User entered '18 Mar 2021 06:25:35'	System	18 Mar 2021 10:25:41

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-25T08:07:50-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '34e8cf56-8ecf-4f61-9b2e-8805f5d53a0a'	System	25 Mar 2021 12:07:58
User entered 'No (N)'	System	25 Mar 2021 12:07:58

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-25T08:07:52-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '34e8cf56-8ecf-4f61-9b2e-8805f5d53a0a'	System	25 Mar 2021 12:07:58
User entered 'No (N)'	System	25 Mar 2021 12:07:58

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-25T08:07:55-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '34e8cf56-8ecf-4f61-9b2e-8805f5d53a0a' User entered '25 Mar 2021 08:07:55'	System	25 Mar 2021 12:07:58
	System	25 Mar 2021 12:07:58

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-01T03:41:44-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ae2acb4e-2295-43a9-ae95-9f3cad66e918'	System	01 Apr 2021 07:41:53
User entered 'No (N)'	System	01 Apr 2021 07:41:53



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-01T03:41:47-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ae2acb4e-2295-43a9-ae95-9f3cad66e918'	System	01 Apr 2021 07:41:53
User entered 'No (N)'	System	01 Apr 2021 07:41:53

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-01T03:41:51-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'ae2acb4e-2295-43a9-ae95-9f3cad66e918'	System	01 Apr 2021 07:41:53
User entered '01 Apr 2021 03:41:51'	System	01 Apr 2021 07:41:53

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-08T05:47:24-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc0e2039-ecab-4009-bf5d-429e31f2973a'	System	08 Apr 2021 09:47:34
User entered 'No (N)'	System	08 Apr 2021 09:47:34

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-08T05:47:27-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc0e2039-ecab-4009-bf5d-429e31f2973a'	System	08 Apr 2021 09:47:34
User entered 'No (N)'	System	08 Apr 2021 09:47:34

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-08T05:47:29-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'cc0e2039-ecab-4009-bf5d-429e31f2973a'	System	08 Apr 2021 09:47:34
User entered '08 Apr 2021 05:47:29'	System	08 Apr 2021 09:47:34



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-15T06:05:29-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '5ed8bfa9-6e61-4cf5-83ab-57b294e1f9d4'	System	15 Apr 2021 10:05:40
User entered 'No (N)'	System	15 Apr 2021 10:05:40

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-15T06:05:32-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '5ed8bfa9-6e61-4cf5-83ab-57b294e1f9d4'	System	15 Apr 2021 10:05:40
User entered 'No (N)'	System	15 Apr 2021 10:05:40

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-15T06:05:35-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '5ed8bfa9-6e61-4cf5-83ab-57b294e1f9d4'	System	15 Apr 2021 10:05:40
User entered '15 Apr 2021 06:05:35'	System	15 Apr 2021 10:05:40

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-22T00:02:37-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'dee561a7-f3db-4fbd-8f4f-90689086271f' User entered 'No (N)'	System	22 Apr 2021 04:03:21
	System	22 Apr 2021 04:03:21

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-22T00:02:39-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'dee561a7-f3db-4fbd-8f4f-90689086271f' User entered 'No (N)'	System	22 Apr 2021 04:03:21
	System	22 Apr 2021 04:03:21

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-22T00:02:43-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'dee561a7-f3db-4fbd-8f4f-90689086271f'	System	22 Apr 2021 04:03:21
User entered '22 Apr 2021 00:02:43'	System	22 Apr 2021 04:03:21

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-29T00:02:17-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f21e89cd-b10b-4314-8124-c2cd4e24342f' User entered 'No (N)'	System	29 Apr 2021 04:03:40
	System	29 Apr 2021 04:03:40



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

Have you been exposed to someone with 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 (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-29T00:02:19-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f21e89cd-b10b-4314-8124-c2cd4e24342f' User entered 'No (N)'	System	29 Apr 2021 04:03:40
	System	29 Apr 2021 04:03:40

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-04-29T00:02:23-04:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: 'f21e89cd-b10b-4314-8124-c2cd4e24342f' User entered '29 Apr 2021 00:02:23'	System	29 Apr 2021 04:03:40
	System	29 Apr 2021 04:03:40

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:27:05



**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:27:05

**US3172028**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:27:05
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:27:05



US3172028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:35:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-04T06:05:44-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '7686e780-a20b-4cb3-8611-8e7427764f92'	System	04 Mar 2021 11:06:11
User entered 'No (N)'	System	04 Mar 2021 11:06:11

**US3172028**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:35:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B65AAB29-3FDD-4289-9A5C-7CE60E340EC0)', Time: '2021-03-04T06:06:04-05:00', User OID: 'PatientReportedOutcome (US3172028)', ODM File OID: '7686e780-a20b-4cb3-8611-8e7427764f92'	System	04 Mar 2021 11:06:11
User entered '04 Mar 2021 06:06:04'	System	04 Mar 2021 11:06:11

US3172028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:56:17
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	04 Nov 2020 14:42:44

US3172028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered '3 Nov 2020'	Mariete Rendon (b) (4)	04 Nov 2020 14:42:44
	(b) (4)	

US3172028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	04 Nov 2020 14:42:44
	(b) (4)	

US3172028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	04 Nov 2020 14:42:44
	(b) (4)	

US3172028

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:56:17
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	04 Nov 2020 14:46:26
	(b) (4)	

**US3172028**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:05:41
User entered 'I'	System	04 Nov 2020 14:46:26



US3172028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:08:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:13:52

US3172028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:08:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '07 Dec 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:13:52

US3172028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:08:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	07 Dec 2020 20:13:52
	(b) (4)	

US3172028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:08:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	07 Dec 2020 20:13:52
	(b) (4)	

US3172028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:08:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:13:57

US3172028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User entered 'I'	System	07 Dec 2020 20:13:57

US3172028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	29 Jan 2021 22:12:13

US3172028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '05 Jan 2021'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:12:13
	(b) (4)	



US3172028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	29 Jan 2021 22:12:13
	(b) (4)	

US3172028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:12:13
	(b) (4)	

US3172028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
Signature has been broken.	(b) (4) Jessie Downs (b) (4)	07 Apr 2021 20:24:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jessie Downs (b) (4)	07 Apr 2021 20:24:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	29 Jan 2021 22:12:37

**US3172028**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User entered 'I'	System	07 Apr 2021 20:24:36
User entered empty.	System	29 Jan 2021 22:12:37

US3172028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:24:52

US3172028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '06 Feb 2021'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:24:52

US3172028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	07 Apr 2021 20:24:52
	(b) (4)	

US3172028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	07 Apr 2021 20:24:52
	(b) (4)	



US3172028

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	07 Apr 2021 20:25:19
	(b) (4)	

**US3172028**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:57:00
User entered 'I'	System	07 Apr 2021 20:25:19

US3172028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:44

US3172028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:44

US3172028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:44

**US3172028**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	07 Apr 2021 20:33:44

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49



US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

**US3172028**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:33:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

**US3172028**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:33:24**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49



US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

**US3172028**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:33:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:33:49

US3172028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:55

US3172028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:55

US3172028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:58



US3172028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:58

US3172028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:33:58

**US3172028**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:33:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 20:33:58

US3172028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:26:01

**US3172028**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 20:26:01

US3172028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:26:24

US3172028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '07 Apr 2021'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:26:24

US3172028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:26:24



US3172028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:26:24

US3172028

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:26:35

**US3172028**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 20:26:35

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Jan 2021 22:13:24
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '28 Jan 2021'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:13:24
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:13:24
	(b) (4)	

**US3172028**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 22:13:24

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:50:10
User entered '06 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:22:30
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:22:30
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). User signature succeeded.	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 18:57:29
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 17:57:51
User entered '22 Dec 2020'	Mark Kutner (b) (4) (b) (4) (b) (4)	16 Feb 2021 14:55:55
	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 22:14:31



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	22 Mar 2021 18:30:31
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:31:59

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Jan 2021 22:14:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Apr 2021 19:22:30
	(b) (4)	
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	Jessie Downs (b) (4)	07 Apr 2021 18:57:10
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	22 Mar 2021 18:30:31
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:31:59

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User closed query 'Per IRT, subject was unblinded on 28JAN2021. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:50:13
Query 'Per IRT, subject was unblinded on 28JAN2021. Please review and reconcile.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:22:55
User entered '28 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:22:30
User opened query 'Per IRT, subject was unblinded on 28JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:06:50
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:30:31
User entered '12 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '28 Jan 2021'	(b) (4) Jessie Downs (b) (4) (b) (4)	29 Jan 2021 22:14:31

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	29 Jan 2021 22:14:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	29 Jan 2021 22:14:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	29 Jan 2021 22:14:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
Signature has been broken.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:30:31
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	22 Mar 2021 18:30:31
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	29 Jan 2021 22:14:31
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '1'	System	29 Jan 2021 22:14:31

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:33:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'I'	System	22 Mar 2021 18:30:31
User entered empty.	System	29 Jan 2021 22:14:31

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '093.2' kg	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	22 Mar 2021 18:32:49
DataPoint set to visible.	System	22 Mar 2021 18:30:31

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '093.2' kg	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	22 Mar 2021 18:32:49
DataPoint set to visible.	System	22 Mar 2021 18:30:31



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '12 Mar 2021'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '09:50'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '12 Mar 2021 09:50'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '37.0' C	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '73'	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'bpm'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '18'	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'breaths/min'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '138'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mmHg'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '79'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mmHg'	System	22 Mar 2021 18:32:49



US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '093.2' kg	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered empty.	System	22 Mar 2021 18:32:49
DataPoint set to visible.	System	22 Mar 2021 18:30:31

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '12 Mar 2021'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '11:52'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '12 Mar 2021 11:52'	System	22 Mar 2021 18:32:49



US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '36.5' C	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '65'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'bpm'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '16'	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'breaths/min'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '139'	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	



US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mmHg'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '92'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:32:49
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mmHg'	System	22 Mar 2021 18:32:49

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	22 Mar 2021 18:30:46
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '12 Mar 2021'	Jessie Downs (b) (4)	22 Mar 2021 18:30:46
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	22 Mar 2021 18:31:18
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:31:18
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:31:18
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'mRNA-1273'	System	22 Mar 2021 18:31:18
DataPoint set to visible.	System	22 Mar 2021 18:30:31

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '12 Mar 2021'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:31:18
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '11:22'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:31:18
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '12 Mar 2021 11:22'	System	22 Mar 2021 18:31:18

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4)	22 Mar 2021 18:31:18
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'ONCE'	System	22 Mar 2021 18:31:18

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 18:31:18

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Jan 2021 22:14:57
	(b) (4)	



US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '28 Jan 2021'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:14:57
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '11:26'	Jessie Downs (b) (4)	29 Jan 2021 22:14:57
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '28 Jan 2021 11:26'	System	29 Jan 2021 22:14:57

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:15:09
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '28 Jan 2021'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:15:09
	(b) (4)	

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '11:27'	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 22:15:09
	(b) (4)	

**US3172028**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:33:24**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered '28 Jan 2021 11:27'	System	29 Jan 2021 22:15:09

US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:31:24
	(b) (4)	



US3172028

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:41
User entered 'I'	System	22 Mar 2021 18:31:24

US3172028

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:33:37
	(b) (4)	

US3172028

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '19 Mar 2021'	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:33:37
	(b) (4)	

US3172028

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	22 Mar 2021 18:33:37
	(b) (4)	

US3172028

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	22 Mar 2021 18:33:37
	(b) (4)	

US3172028

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	22 Mar 2021 18:33:41
	(b) (4)	

**US3172028**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User entered 'I'	System	22 Mar 2021 18:33:41

**US3172028**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:04
User entered 'I'	System	22 Mar 2021 18:33:41
DataPoint set to visible.	System	22 Mar 2021 18:33:41



US3172028

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:06:54

US3172028

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:06:54

US3172028

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:06:54

**US3172028**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:33:24**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	19 Apr 2021 20:06:54

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '07:36'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18



**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 07:36'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '60'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 20:08:18



US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '120'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '10:26'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18



**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 10:26'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '70'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 20:08:18



US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '120'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '70'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:18

**US3172028**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 20:08:18

US3172028

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:25

US3172028

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:25

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:57

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:08:57



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:57

**US3172028**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:33:24**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	19 Apr 2021 20:08:57
DataPoint set to visible.	System	22 Mar 2021 18:33:41

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '12 Apr 2021'	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:08:57

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '09:56'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:08:57

**US3172028**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:33:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 09:56'	System	19 Apr 2021 20:08:57

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:08:57

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Apr 2021 20:08:57

US3172028

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Apr 2021 20:08:57



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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:09:03

**US3172028**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:09:03

US3172028

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:31:06

US3172028

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered '19 Apr 2021'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:31:06

US3172028

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:31:06

US3172028

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:31:06

US3172028

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:31:10

**US3172028**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:33:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 16:31:10



US3172028

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:33:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:26
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	05 Jan 2021 21:22:12
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	01 Sep 2020 13:45:38
	(b) (4)	

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:23:30
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:50:15
User entered	System	06 Jan 2021 15:57:16
'USA-US118-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	06 Jan 2021 15:57:16

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:27:26
User closed query 'Per CDM : Please specify the type of Arrhythmia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Kutner (b) (4) (b) (4)	05 Mar 2021 06:43:52 03 Mar 2021 13:48:53
User coded data point as SOC: Cardiac disorders, HLTG: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Paroxysmal arrhythmia, LLT: Paroxysmal arrhythmia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 01:32:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 01:32:12
Query 'Per CDM : Please specify the type of Arrhythmia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	23 Feb 2021 15:24:39
Data point term sent to Coder	System	23 Feb 2021 15:24:29
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	23 Feb 2021 15:24:28
User entered 'CARDIAC ARRHYTHMIA paroxysmal' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Feb 2021 15:24:28
User opened query 'Per CDM : Please specify the type of Arrhythmia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:45:51
User closed query 'Per DM CLR: Please specify the type of Arrhythmia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:45:32

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:40
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:37
Query 'Per DM CLR: Please specify the type of Arrhythmia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	30 Jan 2021 15:26:02
User opened query 'Per DM CLR: Please specify the type of Arrhythmia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:03:06
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 21:29:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 21:29:31
Data point term sent to Coder	System	05 Jan 2021 21:28:35
User entered 'Cardiac Arrhythmia'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:50:46
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:50:48
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:50:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:50:52
User entered '08 Dec 2020'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07



US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:50:54
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:33:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:50:56
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:28:10
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
DataPoint Un-verified.	Jessie Downs (b) (4)	23 Feb 2021 15:20:58
	(b) (4)	
User entered '11 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Feb 2021 15:20:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:50:58
User entered '12 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07
	(b) (4)	

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:33:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

US3172028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:23:34
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 'Data updated' (Site from Safety).	Mariete Rendon (b) (4)	20 Apr 2021 19:32:21
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)	16 Apr 2021 09:23:03
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered '08 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed 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)	22 Apr 2021 14:19:26
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. ' answered with 'Medical Records sent to safety.' (Site from Safety).	Mariete Rendon (b) (4)	21 Apr 2021 20:13:00
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 Apr 2021 09:24:48
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.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:24:42
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)	16 Apr 2021 09:24:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4)	18 Feb 2021 19:54:16
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:54:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:37
User closed query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:01:23
Query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:54:34
User opened query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:47:54
User entered '12 Dec 2020'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:08:54
User closed query 'Should this be no? Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:08:52
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
Query 'Should this be no? Please verify and update as needed.' answered by data change (Site from CRA).	System	23 Feb 2021 15:21:20
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Feb 2021 15:21:20
	(b) (4)	
User opened query 'Should this be no? Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 19:52:34
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:50
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:51:37
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 19:33:22
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'Unknown at this time pending Medical records.' (Site from System).	Mariete Rendon (b) (4)	05 Jan 2021 21:28:35
	(b) (4)	
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	05 Jan 2021 21:28:07
User entered empty.	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:23:42
User closed query 'PV Query: Please clarify medical history of theanine dycicalin or confirm this should be added with concomitant medications.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:23:37
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4)	20 Apr 2021 19:38:24
Query 'PV Query: Please clarify medical history of theanine dycicalin or confirm this should be added with concomitant medications.' answered with 'Data updated.' (Site from Safety).	Mariete Rendon (b) (4)	20 Apr 2021 19:38:13
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:25:36
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.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:25:29
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)	16 Apr 2021 09:23:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify medical history of theanine dycicalin or confirm this should be added with concomitant medications.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:22:43
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'I'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:28:23
User closed query 'Per CDM: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	05 Mar 2021 06:44:16
	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
Query 'Per CDM: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	23 Feb 2021 15:25:02
	(b) (4)	
User opened query 'Per CDM: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:46:57
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:46:41
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:54:35
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:37
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Pending medical records. ' (Site from DM).	Jessie Downs (b) (4)	30 Jan 2021 15:26:39
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:03:15
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:48:41
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. Please leave query unanswered information is available, or if no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:48:29
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:28:39
User closed query 'Per DM CLR: Narrative = ON 08DEC2020 A CHEST SINGLE VIEW WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:41:45
User closed query 'Per DM CLR: Narrative = HYPOMAGNESEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:41:38
User closed query 'Per DM CLR: Narrative = EKGS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:41:36
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:23:43

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered information is available, or if no results are available, please confirm in your response. ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:23:37
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. Please leave query unanswered information is available, or if not done or no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:37:41
User closed query 'PV Query: In case narrative, the EKG showed evidence of rapid A.F.S and PVE. Please clarify results of EKG.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:37:35
User closed query 'PV Query: Tex Seven was described in case narrative, please clarify.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:37:31
User closed query 'PV Query: In case narrative, subject was screened for COVID-19 on 08 Dec 2020. Please specify type of screening performed.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:37:26
User closed query 'PV Query: Please provide reason why subject will not participate to receive mRNA-1273.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:37:22
Query 'Per DM CLR: Narrative = ON 08DEC2020 A CHEST SINGLE VIEW WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Data updated in Con Proc page' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:35:06
Query 'Per DM CLR: Narrative = EKGS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Data updated in ConProc page' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:34:53

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = HYPOMAGNESEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'A/E entered, please see A/E page' (Site from DM).	Mariete Rendon (b) (4)	12 Apr 2021 19:25:18
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. Please leave query unanswered information is available, or if not done or no results are available, please confirm in your response. ' answered with 'Narrative data updated' (Site from Safety).	Mariete Rendon (b) (4)	12 Apr 2021 19:25:00
Query 'PV Query: In case narrative, the EKG showed evidence of rapid A.F.S and PVE. Please clarify results of EKG.' answered with 'Narrative Data updated.' (Site from Safety).	Mariete Rendon (b) (4)	12 Apr 2021 19:24:28



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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS HOSPITALIZED DUE TO COMPLICATION OF CARDIAC ARRYTHMIA MANIFESTED WITH PALPITATION STARTED ON 08DEC2020 SINCE 23:42. SUBJECT DENIES CHEST PAIN OR SHORTNESS OF BREATHE. AT ER EKGS SHOW EVIDENCE OF RAPID A.F.S. EKG results: Sinus Rythm with frequent ventricular premature complexes , left atrial enlargement, moderate st depression, abnormal ECG PVE AND HYPOMAGNESEMIA. SUBJECT WITH HISTORY OF HYPERTENSION, DIABETES TYPE II, ALCOHOL AND COCAINE. ON ADMISSION SUBJECT WAS TESTED FOR TOX SCREEN AND IT WAS POSITIVE FOR BENZODIAPEM AND COCAINE. PATIENT STARTED WITH ANTICOAGULANT, ELIQUIS 5MG TWICE A DAY AND DILTRAZEM 180MG FoR RATE CONTROL. ON 08DEC2020 A CHEST SINGLE VIEW WAS PERFORMED AND THE IMPRESSION WAS NO ACUTE ABNORMALITY. ON PHYSICAL EXAM SUBJECT WAS ALERT, WELL NOURISHED NO ACUTE DISTRESS. SARS-COV-2 COVID-19 SCREENING DONE 08DEC2020 RESULTS NOT DETECTED.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Apr 2021 19:23:57
Query 'PV Query: Tex Seven was described in case narrative, please clarify.' answered with 'Data corrected to Tox screen' (Site from Safety).	Mariete Rendon (b) (4)	12 Apr 2021 19:16:49
Query 'PV Query: In case narrative, subject was screened for COVID-19 on 08 Dec 2020. Please specify type of screening performed.' answered with 'Data updated in narrative' (Site from Safety).	Mariete Rendon (b) (4)	12 Apr 2021 19:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS HOSPITALIZED DUE TO COMPLICATION OF CARDIAC ARRYTHMIA MANIFESTED WITH PALPITATION STARTED ON 08DEC2020 SINCE 23:42. SUBJECT DENIES CHEST PAIN OR SHORTNESS OF BREATHE. AT ER EKGS SHOW EVIDENCE OF RAPID A.F.S. PVE AND HYPOMAGNESEMIA. SUBJECT WITH HISTORY OF HYPERTENSION, DIABETES TYPE II, ALCOHOL AND COCAINE. ON ADMISSION SUBJECT WAS TESTED FOR TOX SCREEN AND IT WAS POSITIVE FOR BENZODIAPEM AND COCAINE. PATIENT STARTED WITH ANTICOAGULANT, ELIQUIS 5MG TWICE A DAY AND DILTRAZEM180MG FIR RATE CONTROL. ON 08DEC2020 A CHEST SINGLE VIEW WAS PERFORMED AND THE IMPRESSION WAS NO ACUTE ABNORMALITY.. ON PHYSICAL EXAM SUBJECT WAS ALERT, WELL NOURISHED NO ACUTE DISTRESS. SARS-COV-2 COVID-19 SCREENING DONE 08DEC2020 RESULTS NOT DETECTED.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Apr 2021 19:16:06
Query 'PV Query: Please provide reason why subject will not participate to receive mRNA-1273.'	Mariete Rendon (b) (4)	12 Apr 2021 19:14:42
answered with 'I do not understand query. Subject came for decision visit and was dosed.' (Site from Safety).		
Signature has been broken.	Mariete Rendon (b) (4)	12 Apr 2021 19:14:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS HOSPITALIZED DUE TO COMPLICATION OF CARDIAC ARRHYTHMIA MANIFESTED WITH PALPITATION STARTED ON 08DEC2020 SINCE 23:42. SUBJECT DENIES CHEST PAIN OR SHORTNESS OF BREATHE. AT ER EKG'S SHOW EVIDENCE OF RAPID A.F.S. PVE AND HYPOMAGNESEMIA. SUBJECT WITH HISTORY OF HYPERTENSION, DIABETES TYPE II, ALCOHOL AND COCAINE. ON ADMISSION SUBJECT WAS TESTED FOR ToX SCREEN AND IT WAS POSITIVE FOR BENZODIAPEM AND COCAINE. PATIENT STARTED WITH ANTICOAGULANT, ELIQUIS 5MG TWICE A DAY AND DILTRAZEM180MG FIR RATE CONTROL. ON 08DEC2020 A CHEST SINGLE VIEW WAS PERFORMED AND THE IMPRESSION WAS NO ACUTE ABNORMALITY.. ON PHYSICAL EXAM SUBJECT WAS ALERT, WELL NOURISHED NO ACUTE DISTRESS. COVID SCREENING DONE 08DEC2020 RESULTS NOT DETECTED.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:14:05
User opened query 'Per DM CLR: Narrative = ON 08DEC2020 A CHEST SINGLE VIEW WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:16:09
User opened query 'Per DM CLR: Narrative = HYPOMAGNESEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:15:56
User opened query 'Per DM CLR: Narrative = EKG'S. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:15:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. Please leave query unanswered information is available, or if not done or no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:44:17
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. Please leave query unanswered information is available, or if no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:43:52
User closed query 'PV Query: According to case narrative, subject has a history of cocaine usage. Please update subject's medical history to include cocaine usage.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:23:23
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. Please leave query unanswered information is available, or if no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:23:19
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. Please leave query unanswered information is available, or if not done or no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:22:51
Query 'PV Query: According to case narrative, subject has a history of cocaine usage. Please update subject's medical history to include cocaine usage.' answered with 'Medical history was updated. See line #11.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 15:47:57

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: In case narrative, the EKG showed evidence of rapid A.F.S and PVE. Please clarify results of EKG.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:31:59
User opened query 'PV Query: Tex Seven was described in case narrative, please clarify.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:31:22
User opened query 'PV Query: In case narrative, subject was screened for COVID-19 on 08 Dec 2020. Please specify type of screening performed.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:31:12
User opened query 'PV Query: According to case narrative, subject has a history of cocaine usage. Please update subject's medical history to include cocaine usage.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:30:53
User opened query 'PV Query: Please provide reason why subject will not participate to receive mRNA-1273.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:29:07
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:27:59
Query '' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:27:05
User opened query '' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:26:55
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:26:55
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	

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Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered information is available, or if no results are available, please confirm in your response.' answered with 'pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	25 Feb 2021 19:25:18
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. Please leave query unanswered information is available, or if not done or no results are available, please confirm in your response.' answered with 'pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	25 Feb 2021 19:25:15
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	25 Feb 2021 19:25:12
User entered 'subject was hospitalized due to complication of cardiac arrhythmia manifested with palpitation started on 08dec2020 since 11:00 am. subject denies chest pain or shortness of breathe. at ER ekgs show evidence of rapid a.f.s. pve and hypomagnesemia. subject with history of hypertension, diabetes type ii, alcohol and cocaine. on admission subject was tested for tex seven and it was positive for benzodapem and cocaine. patient started with anticoagulant, Eliquis 5mg twice a day and diltrazem 180mg fir rate control. on 08dec2020 a chest single view was performed and the impression was no acute abnormality.. on physical exam subject was alert, well nourished no acute distress. Covid screening done 08dec2020 results not detected.' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Feb 2021 22:37:57
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 19:54:53

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Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 19:51:37
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. Please leave query unanswered information is available, or if no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 21:58:08
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. Please leave query unanswered information is available, or if not done or no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 21:58:00
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)	02 Feb 2021 17:11:00
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)	02 Feb 2021 17:10:58
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 21:40:18

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 21:39:12
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:48:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:47:41
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:47:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:56:44
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:56:42



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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:56:41
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pending medical records. ' (Site from Safety).	Jessie Downs (b) (4)	30 Jan 2021 15:26:53
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Pending medical records. ' (Site from Safety).	Jessie Downs (b) (4)	30 Jan 2021 15:26:48
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Pending medical records. ' (Site from Safety).	Jessie Downs (b) (4)	30 Jan 2021 15:26:44
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)	21 Jan 2021 16:20:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:20:04

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Folder: Adverse Events

Form: Adverse Events (1)

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:19:50
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)	19 Jan 2021 14:01:27
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)	19 Jan 2021 14:01:25
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:55:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:54:45
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)	14 Jan 2021 19:48:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 19:47:35
User entered 'On safety call Day 149 subject reported, went to the hospital due to cardiac arrhythmia and had a catheter procedure done. Subject was unable to provide more information at this time conmed updated with patient. Medical records will be requested.'	Mariete Rendon (b) (4)	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:28:07

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:28:07

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 15:21:20
User entered '1'	System	05 Jan 2021 21:28:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Paroxysmal arrhythmia, LLT: Paroxysmal arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 01:32:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 01:32:12
	(b) (4)	
Data point term sent to Coder	System	23 Feb 2021 15:24:27
User entered 'cardiac arrhythmia paroxysmal'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'No (N)'	(b) (4)	
	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '05 Dec 2020'	(b) (4)	
	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		23 Feb 2021 15:23:53
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	23 Feb 2021 15:23:53
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Feb 2021 15:23:43
User entered '11:00'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
User entered empty.	System	23 Feb 2021 15:23:53
User entered '05 Dec 2020 11:00'	System	23 Feb 2021 15:23:43

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'No (N)'	(b) (4)	
	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '05 Dec 2020'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	23 Feb 2021 15:23:53
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	23 Feb 2021 15:23:53
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	23 Feb 2021 15:23:43
User entered '14:00'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
User entered empty.	System	23 Feb 2021 15:23:53
User entered '05 Dec 2020 14:00'	System	23 Feb 2021 15:23:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	(b) (4)	
	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '0'	(b) (4)	
	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:36:32
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:36:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	23 Feb 2021 15:23:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:42:32
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:36:59
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:36:32
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:36:32
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:17:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '1'	Jessie Downs (b) (4) (b) (4)	23 Feb 2021 15:23:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Feb 2021 15:23:43
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
User entered '0'	System	23 Feb 2021 15:23:43



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56
User entered '1'	System	23 Feb 2021 15:23:43

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:49:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:08
User entered 'USA-US118-2021-mRNA-1273-P301000014'	System	13 Apr 2021 14:55:04
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:04
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 14:55:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:56:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:56:43
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:15:41
User entered 'USA-US118-2021-mRNA-1273-P301000001'	(b) (4), (b) (6)	08 Apr 2021 13:15:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 20:12:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 20:12:46
Data point term sent to Coder	System	07 Apr 2021 20:11:50
User entered 'cardiac arrhythmia'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '05 Apr 2021'	Jessie Downs (b) (4)	07 Apr 2021 20:11:47
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User entered empty.	System	07 Apr 2021 20:11:47

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '06 Apr 2021'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	Jessie Downs (b) (4)	07 Apr 2021 20:11:47
	(b) (4)	

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User entered empty.	System	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Apr 2021 20:12:11
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Apr 2021 20:11:47
User entered 'Yes (Y)'	Jessie Downs (b) (4)	07 Apr 2021 20:11:47
	(b) (4)	



US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		07 Apr 2021 20:12:11
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		07 Apr 2021 20:12:11
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:12:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Apr 2021 20:11:47
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '05 Apr 2021'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '06 Apr 2021'	Jessie Downs (b) (4)	07 Apr 2021 20:11:47
	(b) (4)	

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47

US3172028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify medical history of theanine dycicalin or confirm this should be added with concomitant medications.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:01:03
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'I'	Jessie Downs (b) (4)	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 20:11:47



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	07 Apr 2021 20:17:00
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	07 Apr 2021 20:16:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4)	07 Apr 2021 20:11:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	07 Apr 2021 20:17:00
	(b) (4)	
User entered 'on phone call 239 day subject referred been at Baptist hospital due to another episode of cardiac arrhythmia. medical records will be requested.' reason for change: Data Entry Error	Jessie Downs (b) (4)	07 Apr 2021 20:16:02
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	07 Apr 2021 20:11:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify medical history of theanine dycicalin or confirm this should be added with concomitant medications. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:00:52
User opened query 'PV Query: Please clarify medical history of theanine dycicalin or confirm this should be added with concomitant medications. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:55:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'ON PHONE CALL 239 DAY SUBJECT REFERRED BEEN AT BAPTIST HOSPITAL DUE TO ANOTHER EPISODE OF CARDIAC ARRHYTHMIA. from 05apr2021 to 06apr2021. he was discharged by 4 pm. subject had another cardiac arrhythmia episode "like he had before" reason why he decided to go to the er. he received treatment. he doesnt recall the name of the medication and he was prescribed with new medication that he placed at the pharmacy. pending report information. MEDICAL RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error	Jessie Downs (b) (4)	07 Apr 2021 20:23:40
User entered 'ON PHONE CALL 239 DAY SUBJECT REFERRED BEEN AT BAPTIST HOSPITAL DUE TO ANOTHER EPISODE OF CARDIAC ARRHYTHMIA. MEDICAL RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error	Jessie Downs (b) (4)	07 Apr 2021 20:17:00
User entered empty.	Jessie Downs (b) (4)	07 Apr 2021 20:11:47

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User entered 'I'	System	07 Apr 2021 20:11:47

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User entered 'I'	System	07 Apr 2021 20:11:47

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:50:24
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:07
User entered '0'	System	07 Apr 2021 20:11:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:58:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:58:05
Data point term sent to Coder	System	09 Apr 2021 14:49:01
User entered 'Worsening of hypertension'	(b) (4), (b) (6)	09 Apr 2021 14:48:19



US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '08 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		09 Apr 2021 14:49:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 14:49:48
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Apr 2021 14:48:19
User entered '23:42'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:33:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User entered empty.	System	09 Apr 2021 14:49:48
User entered '08 Dec 2020 23:42'	System	09 Apr 2021 14:48:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '10 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 14:48:19



US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Apr 2021 14:49:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 14:49:48
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Apr 2021 14:48:19
User entered '20:00'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:33:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User entered empty.	System	09 Apr 2021 14:49:48
User entered '10 Dec 2020 20:00'	System	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19



US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19



US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 14:49:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 14:49:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	09 Apr 2021 14:49:48
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 14:48:19
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:48:19

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User entered '0'	System	09 Apr 2021 14:48:19



**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43
User entered 'I'	System	09 Apr 2021 14:48:19

US3172028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:43

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:33:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B1 deficiency, LLT: Vitamin B1 deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:40:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:40:52
Data point term sent to Coder	System	09 Apr 2021 14:57:25
User entered 'Thiamine Deficiency'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '08 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 14:56:54



US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:33:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User entered empty.	System	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '10 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:33:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User entered empty.	System	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54



US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54



US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:56:54



US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:56:54

US3172028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:33:24

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User entered '0'	System	09 Apr 2021 14:56:54

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49
User entered 'I'	System	09 Apr 2021 14:56:54

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:49

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:33:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:11:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:11:44
Data point term sent to Coder	System	09 Apr 2021 14:59:30
User entered 'Worsening of Diabetes type 2'	(b) (4), (b) (6)	09 Apr 2021 14:58:38



US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '08 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:33:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User entered empty.	System	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '10 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 14:58:38



US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User entered empty.	System	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38



US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38



US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'l'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:58:38

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User entered '0'	System	09 Apr 2021 14:58:38



**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58
User entered 'I'	System	09 Apr 2021 14:58:38

US3172028

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:58

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:33:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:33:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:18:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:18:29
Data point term sent to Coder	System	09 Apr 2021 15:05:47
User entered 'Hypomagnesemia'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '08 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 15:05:43



US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User entered empty.	System	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '10 Dec 2020'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:33:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User entered empty.	System	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43



US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43



US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:05:43



**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

US3172028

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:33:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:33:53
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:05:43

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User entered '0'	System	09 Apr 2021 15:05:43

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07
User entered 'I'	System	09 Apr 2021 15:05:43

**US3172028**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:51:07

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:33:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 14:34:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:34:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered 'Yes (Y)'	(b) (4)	
	Mariete Rendon (b) (4)	11 Aug 2020 15:10:59
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 15:13:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 15:13:14
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 15:12:36
User entered 'Metformin'	Mariete Rendon (b) (4)	11 Aug 2020 15:11:42
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Diabetes type 2'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '1000'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	11 Aug 2020 15:11:42
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:33:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:56:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:11:42
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 15:13:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 15:13:52
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 15:13:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 15:11:42
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:11:42
	(b) (4)	

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 15:11:42

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 15:11:42



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 15:11:42

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 15:13:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 15:13:38
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 15:12:36
User entered 'Losartan'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Hypertension'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '12.5'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:56:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:12:21
User entered 'UN UNK 2010'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	28 Apr 2021 17:03:47
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 17:03:47
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	28 Apr 2021 17:03:47
	(b) (4)	
User entered '10 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 17:03:47
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 15:12:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 15:12:33
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	11 Aug 2020 15:12:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 15:12:21
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 15:12:21
	(b) (4)	



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User entered '1'	System	11 Aug 2020 15:12:21

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User entered '1'	System	11 Aug 2020 15:12:21

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:36:46
User entered '804 (804)'	System	11 Aug 2020 15:12:21

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 15:15:14
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Aug 2020 15:15:14
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 15:14:41
User entered 'Amlodipine'	Mariete Rendon (b) (4)	11 Aug 2020 15:13:40
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Hypertension'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '2.5'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'other (OTHER)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Bed time'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:56:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 15:13:40
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 15:13:40

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:13:40

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:13:40

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:13:40

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User closed query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the correct name of the medication (consider: DILTIAZEM). Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:56:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:29:48
Data point term sent to Coder	System	06 Feb 2021 19:29:31
Query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the correct name of the medication (consider: DILTIAZEM). Update eCRF as appropriate.	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:29:11
' answered with 'Data was updated' (Site from DM).		
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:29:01
User entered 'DILTIAZEm' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:29:01
User opened query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the correct name of the medication (consider: DILTIAZEM). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:49:54

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:39:38
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 Jan 2021 21:39:38
Data point term sent to Coder	System	05 Jan 2021 21:36:45
User entered 'Diltiazepam'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Atrial Fibrillation'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '180'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	05 Jan 2021 21:35:52
	(b) (4)	

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '10 Dec 2020'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 13:09:37
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'still ongoing' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:43:11
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:27:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:35:52

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:35:52

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:35:52

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:35:52



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:39:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:39:39
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 21:37:48
User entered 'clopidrogel'	Mariete Rendon (b) (4)	05 Jan 2021 21:37:36
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:57:05
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Subject is taking medication due to cardiac arrhythmia AE ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:30:25
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:51:24
User entered 'Coronary artery disease'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '75'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:33:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	05 Jan 2021 21:37:36
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:37:36
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:37:36

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:37:36



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:37:36

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:37:36

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:39:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:39:38
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 21:38:49
User entered 'Folic Acid'	Mariete Rendon (b) (4)	05 Jan 2021 21:38:29
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Nutritional supplement'	Mariete Rendon (b) (4)	05 Jan 2021 21:38:29
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '1'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'once daily (QD)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:38:29
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	28 Apr 2021 17:04:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 17:04:15
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	05 Jan 2021 21:38:29
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	28 Apr 2021 17:04:15
	(b) (4)	
User entered '05 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 17:04:15
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	05 Jan 2021 21:38:29
	(b) (4)	



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:38:29

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:38:29

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:38:29

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:38:29

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:57:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:57:36
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 21:39:51
User entered 'Carvedilol'	Mariete Rendon (b) (4)	05 Jan 2021 21:39:28
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:57:28
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Subject is taking medication due to Cardiac arrhythmia AE' (Site from DM).	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:31:52
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:51:39
User entered 'Cardiac Heart Failure'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '3.125'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	05 Jan 2021 21:39:28
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	05 Jan 2021 21:39:28
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	05 Jan 2021 21:39:28
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:39:28
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	05 Jan 2021 21:39:28
	(b) (4)	

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Jan 2021 21:39:28

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:39:28

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:39:28

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 08:24:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 08:24:54
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	06 Feb 2021 19:33:33
	Jessie Downs (b) (4)	06 Feb 2021 19:32:35
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:41:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:41:42
	(b) (4)	
Data point term sent to Coder User entered 'Atorvastatin'	System	05 Jan 2021 21:40:52
	Mariete Rendon (b) (4)	05 Jan 2021 21:40:48
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User closed query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis/Prevention was included in the medical indication record. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:33:36
Query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis/Prevention was included in the medical indication record. Please update as appropriate or provide clarification. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 21:42:53
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 21:42:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 21:42:39
User opened query 'Per DM CLR: Prophylaxis = No. However, the term Prophylaxis/Prevention was included in the medical indication record. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:26:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User closed query 'Per DM CLR: Please update CM indication term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the applicable eCRF as necessary. ' (Site from DM).	(b) (4)	11 Feb 2021 21:00:30
	(b) (4), (b) (6)	
Query 'Per DM CLR: Please update CM indication term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the applicable eCRF as necessary.	Jessie Downs (b) (4)	06 Feb 2021 19:32:44
' answered with 'Data was updated.' (Site from DM).	(b) (4)	
User entered 'Cardiovascular disease precaution' reason for change: Data Entry Error	Jessie Downs (b) (4)	06 Feb 2021 19:32:35
	(b) (4)	
User opened query 'Per DM CLR: Please update CM indication term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the applicable eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:51:55
User entered 'Cardiac'	Mariete Rendon (b) (4)	05 Jan 2021 21:40:48
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '40'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	05 Jan 2021 21:40:48
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:40:48
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:40:48

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:40:48

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:40:48

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:40:48



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:42:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:42:32
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 21:41:53
User entered 'Glimiperide'	Mariete Rendon (b) (4)	05 Jan 2021 21:41:41
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Diabetes type 2'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '1'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	05 Jan 2021 21:41:41
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	05 Jan 2021 21:41:41
	(b) (4)	

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:41:41
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	05 Jan 2021 21:41:41
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:41:41

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Jan 2021 21:41:41



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:41:41

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:41:41

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:44:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:44:38
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 21:43:55
User entered 'Eliquis'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:02
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'prophylaxis atrial fibrillation'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:02
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '5'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:02
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:02
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:02
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	05 Jan 2021 21:43:02
	(b) (4)	



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:33:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:02

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Jan 2021 21:43:02

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:43:02

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:43:02

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:44:38
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Jan 2021 21:44:38
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Jan 2021 21:43:55
User entered 'Simvastatin'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:44
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:01:49
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Subject is taking medication due to Cardiac arrhythmia AE' (Site from DM).	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:33:11
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:52:17
User entered 'Hypercholesterol'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '10'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'mg (mg)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'once daily (QD)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Oral (ORAL)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:33:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	05 Jan 2021 21:43:44
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Mariete Rendon (b) (4)	05 Jan 2021 21:43:44
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered '0'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'Yes (Y)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered empty.	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 14:55:55
User entered 'No (N)'	(b) (4) Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:43:44

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:43:44

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:43:44

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 21:43:44

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HYPERTENSION during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:52:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:52:48
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HYPERTENSION during this timeframe; update Con Med indication or provide clarification. ' answered with 'Please see A/E page.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:38:32
Data point term sent to Coder	System	12 Apr 2021 19:38:05
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:37:54
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HYPERTENSION during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:49:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Feb 2021 14:29:51

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	26 Feb 2021 14:29:51
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	26 Feb 2021 14:28:38
User entered 'Spironolactone'	Jessie Downs (b) (4)	26 Feb 2021 14:28:24
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	12 Apr 2021 19:37:54
	(b) (4)	
User entered 'Worsening HYPERTENSION' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Apr 2021 19:37:54
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'hypertension'	Jessie Downs (b) (4)	26 Feb 2021 14:28:24
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Data corrected' (Site from DM). Signature has been broken.	(b) (4) (b) (4), (b) (6) Mariete Rendon (b) (4) (b) (4)	15 Apr 2021 06:02:19 12 Apr 2021 19:38:43
User entered '25' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:37:54
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Kutner (b) (4) (b) (4)	12 Mar 2021 12:49:13 03 Mar 2021 13:48:53
User entered '10'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'mg (mg)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'other (OTHER)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'daily for 30 days'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Oral (ORAL)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '10 Dec 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	28 Apr 2021 17:04:46
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 17:04:46
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	26 Feb 2021 14:28:24
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	28 Apr 2021 17:04:46
	(b) (4)	
User entered '06 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 17:04:46
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:28:24
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:28:24

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:28:24

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:28:24



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:28:24

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DIABETES TYPE II during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:02:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:02:45
Data point term sent to Coder	System	12 Apr 2021 19:40:08
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:39:10
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DIABETES TYPE II during this timeframe; update Con Med indication or provide clarification. ' answered with 'Please see A/E page' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:39:00
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening DIABETES TYPE II during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:49:38

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 10:46:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 10:46:57
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	03 Mar 2021 13:48:53
Data point term sent to Coder	System	26 Feb 2021 14:29:39
User entered 'jardinace'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	12 Apr 2021 19:39:10
	(b) (4)	
User entered 'Worsening DIABETES TYPE II'	Mariete Rendon (b) (4)	12 Apr 2021 19:39:10
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'diabetes type ii'	Jessie Downs (b) (4)	26 Feb 2021 14:29:16
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '10'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'mg (mg)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'once daily (QD)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Oral (ORAL)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:29:16
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:29:16

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:29:16

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:29:16

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 14:29:16

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:13:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 07:13:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	(b) (4)	26 Feb 2021 14:32:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 14:32:56
Data point term sent to Coder User entered 'magnesium sulfate'	System	26 Feb 2021 14:31:41
	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User closed query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:29
Query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Please see A/E page' (Site from DM).	Mariete Rendon (b) (4)	12 Apr 2021 19:39:40
User opened query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:50:26
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
User entered 'hypomagnesemia'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '2'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'g (g)'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'once (ONCE)'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '08 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '08 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:30:52
	(b) (4)	

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User entered empty.	System	26 Feb 2021 14:30:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User entered empty.	System	26 Feb 2021 14:30:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:04
User entered empty.	System	26 Feb 2021 14:30:52

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:49:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	03 Mar 2021 13:48:53
Data point term sent to Coder User entered 'nitroglycerin'	System Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:36:45 26 Feb 2021 14:35:46

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User closed query 'Per DM CLR: Please note that there is no ConProc matching Con Med # 15 and # 16 indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note that there is no ConProc matching Con Med # 15 and # 16 indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the eCRF as appropriate.' answered with 'Please see conProc log, data updated' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:35
User opened query 'Per DM CLR: Please note that there is no ConProc matching Con Med # 15 and # 16 indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the eCRF as appropriate.' (Site from DM). User signature succeeded.	Mariete Rendon (b) (4)	12 Apr 2021 19:45:36
	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 12:51:11
	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'ct scan test'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0.4'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'once (ONCE)'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'sub lingual'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '09 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '09 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:35:46
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User entered empty.	System	26 Feb 2021 14:35:46

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User entered empty.	System	26 Feb 2021 14:35:46

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:07
User entered empty.	System	26 Feb 2021 14:35:46



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: IODINE THERAPY, ATC: IODINE THERAPY, PRODUCT: IODINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:00:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:00:53
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 19:50:27
Coding entries removed.	Mariete Rendon (b) (4)	12 Apr 2021 19:50:01
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	12 Apr 2021 19:50:01
	(b) (4)	
User entered 'IODINE (80mL)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Apr 2021 19:50:01
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: IODINE THERAPY, ATC: IODINE THERAPY, PRODUCT: IODINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:27:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:27:56
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:37:46
User entered 'iodine'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'computed tomography'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:47
Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'per medical records: LOCM 300-309 MG ML Iodine ML quantity:80' (Site from DM).	Mariete Rendon (b) (4)	12 Apr 2021 19:49:50
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:51:27
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
User entered '300/309'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'once (ONCE)'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '09 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '09 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:37:39
	(b) (4)	

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User entered empty.	System	26 Feb 2021 14:37:39



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User entered empty.	System	26 Feb 2021 14:37:39

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:11
User entered empty.	System	26 Feb 2021 14:37:39

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: REGADENOSON, PRODUCTSYNONYM: LEXISCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 14:40:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 14:40:54
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:39:48
User entered 'lexiscan'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User closed query 'Per DM CLR: Please note that there is no ConProc matching the Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:53
Query 'Per DM CLR: Please note that there is no ConProc matching the Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the eCRF as appropriate. ' answered with 'Data updated in ConPro page' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:50:42
User opened query 'Per DM CLR: Please note that there is no ConProc matching the Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:51:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'nuclear myocardia sect'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:39:35

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0.4'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'once (ONCE)'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered '10 Dec 2020'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	26 Feb 2021 14:39:35
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User entered empty.	System	26 Feb 2021 14:39:35

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User entered empty.	System	26 Feb 2021 14:39:35

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:38:17
User entered empty.	System	26 Feb 2021 14:39:35

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HYPERTENSION during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:12:40
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 Apr 2021 21:12:40
Data point term sent to Coder	System	12 Apr 2021 19:51:28
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HYPERTENSION during this timeframe; update Con Med indication or provide clarification. ' answered with 'Please see A/E page' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:51:20
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:51:02
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HYPERTENSION during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:52:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	03 Mar 2021 13:48:53

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:43:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:43:00
Data point term sent to Coder	System	26 Feb 2021 14:41:55
User entered 'losartan'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	12 Apr 2021 19:51:02
	(b) (4)	
User entered 'Worsening HYPERTENSION' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Apr 2021 19:51:02
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User entered 'hypertension'	Jessie Downs (b) (4)	26 Feb 2021 14:41:48
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '100'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'mg (mg)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'once daily (QD)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Oral (ORAL)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '10 Dec 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:41:48

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:41:48

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:41:48

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 14:41:48

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 18:06:55
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 18:06:55
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:43:01
User entered 'thiamine'	Jessie Downs (b) (4)	26 Feb 2021 14:42:37
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:03:05
Query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Please see A/E page' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:51:54
User opened query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:52:22
User signature succeeded.	Mark Kutner (b) (4) (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'thiamine deficiency'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '100'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'mg (mg)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'once daily (QD)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Oral (ORAL)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '10 Dec 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Yes (Y)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	26 Feb 2021 14:42:37

**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:42:37

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:42:37



US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 14:42:37

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 17:47:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 17:47:49
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:07:16
User entered 'acetaminophen'	Jessie Downs (b) (4)	28 Apr 2021 17:07:09
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'headaches - 2nd dose - SARs'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered '650'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'mg (mg)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 19:37:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 19:37:43
User entered 'once (ONCE)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 19:37:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 17:07:09
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 17:07:09
	(b) (4)	



US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'Oral (ORAL)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 17:07:09
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
User closed query 'Start date is missing and Start date System completely unknown is not checked. Please provide.' (Site from System).		28 Apr 2021 19:37:43
User entered '13 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 19:37:43
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Apr 2021 17:07:09
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 17:07:09
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 19:37:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 19:37:43
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 19:37:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 17:07:09
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 17:07:09
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:00
	(b) (4)	
	(b) (4)	
User entered '13 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 19:37:43
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 17:07:09
	(b) (4)	

US3172028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:33:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:00
User entered 'No (N)'	(b) (4) Jessie Downs (b) (4) (b) (4)	28 Apr 2021 17:07:09



**US3172028**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:33:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:07:09

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:07:09

US3172028

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:33:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:07:09

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:33:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 22:07:53
User closed query 'Per source, subject had a cardiac cath. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:07:51
User closed query 'Per ETRTR, According to SAE Cardiac Arrhythmia, concomitant procedures were done but no concomitant procedure is entered in this page. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:07:49
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 20:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 20:04:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 20:02:59
Query 'Per source, subject had a cardiac cath. Please verify and update as needed.' answered by data change (Site from CRA).	System	25 Feb 2021 20:02:59
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:02:59
User opened query 'Per source, subject had a cardiac cath. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 19:53:54
Query 'Per ETRTR, According to SAE Cardiac Arrhythmia, concomitant procedures were done but no concomitant procedure is entered in this page. Please reconcile.' answered with 'Pending medical records.' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:27:08
User opened query 'Per ETRTR, According to SAE Cardiac Arrhythmia, concomitant procedures were done but no concomitant procedure is entered in this page. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 23:30:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 18:54:26

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered '08 Dec 2020'	(b) (4) Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:05:07

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'cardiac Cath procedure'	(b) (4) Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:05:07

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered 'Adverse Event (AE)'	(b) (4) Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:05:07

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:48:53
User entered empty.	(b) (4) Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:05:07



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '8 Dec 2020'	(b) (4)	
	Mariete Rendon (b) (4)	12 Apr 2021 19:29:53
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'EKG-stress'	(b) (4) Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:29:53

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4)	12 Apr 2021 19:29:53
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:04
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	12 Apr 2021 19:29:53
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered '5 Dec 2020'	(b) (4) Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 19:31:12

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Radiology chest single view XR'	Mariete Rendon (b) (4)	12 Apr 2021 19:31:12
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4)	12 Apr 2021 19:31:12
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Apr 2021 19:31:12
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:09
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '10 Dec 2020'	(b) (4)	
	Mariete Rendon (b) (4)	12 Apr 2021 19:32:08
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:09
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Myocardial spect mult W EF WM'	Mariete Rendon (b) (4)	12 Apr 2021 19:32:08
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:09
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered 'Adverse Event (AE)'	(b) (4)	
	Mariete Rendon (b) (4)	12 Apr 2021 19:32:08
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:09
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Apr 2021 19:32:08
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:12
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered '9 Dec 2020'	(b) (4)	
	Mariete Rendon (b) (4)	12 Apr 2021 19:33:18
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:12
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Radiology: Coronary CTA W CA score Mariete Rendon '	(b) (4)	12 Apr 2021 19:33:18
T\ Func'	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:12
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4)	12 Apr 2021 19:33:18
	(b) (4)	

US3172028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:12
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	12 Apr 2021 19:33:18
	(b) (4)	



**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
User entered '06/Jan/2021 10:57'	(b) (4)	
	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16



**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered '24/Feb/2021 16:25'	(b) (4)	24 Feb 2021 21:25:33
	System	

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:23:44
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:48:53
	(b) (4)	
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 21:25:33

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29



**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:39:11
	(b) (4)	
User entered '05/Mar/2021 10:23'	(b) (4)	
	System	05 Mar 2021 16:23:57

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 10:37:55
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:39:11
	(b) (4)	
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:23:57

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User entered '08/Apr/2021 06:16'	System	08 Apr 2021 13:16:12



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 10:37:55
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 13:16:12

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User entered '13/Apr/2021 10:38'	System	13 Apr 2021 10:38:11

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:04
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 00:07:50
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 10:38:11



**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User entered '14/Apr/2021 00:10'	System	14 Apr 2021 00:10:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 00:10:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered		
'USA-US118-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Yes (Y)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'No (N)'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Mark'	System	06 Jan 2021 15:57:16



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'Kutner'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'FL'	System	06 Jan 2021 15:57:16

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:26:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 15:57:33
User entered 'US'	System	06 Jan 2021 15:57:29

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 13:23:00
User entered '6'	System	14 Apr 2021 00:10:29
User entered '5'	System	13 Apr 2021 10:38:11
User entered '4'	System	08 Apr 2021 13:16:12
User entered '3'	System	05 Mar 2021 16:23:57
Signature has been broken.	System	24 Feb 2021 21:25:33
User entered '2'	System	24 Feb 2021 21:25:33
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 14:55:55
	(b) (4)	
	(b) (4)	
User entered '1'	System	06 Jan 2021 15:57:29

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
	(b) (4)	
User entered '21/Apr/2021 06:22'	System	21 Apr 2021 13:23:00

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:23:00

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'USA-US118-2021-MRNA-1273-P301000014'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Yes (Y)'	System	13 Apr 2021 14:55:04



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Yes (Y)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Mark'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Kutner'	System	13 Apr 2021 14:55:04



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'FL'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
User entered 'US'	System	13 Apr 2021 14:55:28

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:55:28

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'USA-US118-2021-MRNA-1273-P301000014'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Yes (Y)'	System	13 Apr 2021 14:55:04

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Yes (Y)'	System	13 Apr 2021 14:55:04



US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'No (N)'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Mark'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'Kutner'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered 'FL'	System	13 Apr 2021 14:55:04

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
User entered 'US'	System	13 Apr 2021 14:55:28

**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:33:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:55:28



**US3172028**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:33:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:26:21
User entered '13/Apr/2021 10:55'	System	13 Apr 2021 14:55:28

US3172028

Folder: SAE USA-US118-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:55:57
	(b) (4)	
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:26:21
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 14:55:28