

US3722406 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:28:04

All time stamps listed in this document are displayed in GMT

US3722406

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

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[Participant ID](#)

US3722406

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

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US3722406

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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

Visit date (dd MMM yyyy)	28 AUG 2020
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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	SCRN
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US3722406

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:02:40

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Mar 2021 11:02:40

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Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Condition	BENIGN PROSTATE HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Condition	DIZZINESS
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:46 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:46
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	199.6 lb
BMI ( <i>xxx.x</i> )	27.89676 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) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:02:40

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**Occupational Risk**

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**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)**

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**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) 09 Mar 2021 11:02:40

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109122

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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)	28 AUG 2020
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:46
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 16:08
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 11:02:40

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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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 15:33 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 15:33

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

15:07 (24 HR)

Collection date and time (derived)

28 AUG 2020 15:07



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:03	28 AUG 2020 15:03
Nasopharyngeal Swab 2	Yes	15:03	28 AUG 2020 15:03

US3722406

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 16:10

PC Open Date & Time

28 AUG 2020 15:53

PC Close Date & Time

28 AUG 2020 18:23

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	29 AUG 2020 08:36
PC Open Date & Time	28 AUG 2020 19:18
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**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

97.3 °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

29 AUG 2020 22:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:10

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**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

96.8 °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

31 AUG 2020 15:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:14

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

02 SEP 2020 12:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 01:10

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**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

28 AUG 2020 16:12

PC Open Date & Time

28 AUG 2020 15:53

PC Close Date & Time

28 AUG 2020 18:23

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 08:37

PC Open Date & Time

28 AUG 2020 19:18

PC Close Date & Time

29 AUG 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**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

29 AUG 2020 22:45

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**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

30 AUG 2020 12:11

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**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

31 AUG 2020 15:31

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**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

01 SEP 2020 12:14

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**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

02 SEP 2020 12:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**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

04 SEP 2020 01:10

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 16:12
PC Open Date & Time	28 AUG 2020 15:53
PC Close Date & Time	28 AUG 2020 18:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 08:37
PC Open Date & Time	28 AUG 2020 19:18
PC Close Date & Time	29 AUG 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**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 ☒

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:45
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**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 ☒

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**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 ☒

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 15:32
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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 ☒

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EAB) (1725)

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**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  
EAB) (1725)

54 of 1703

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:24
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**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 ☒

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 01:11
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3722406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3722406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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)	30 SEP 2020
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 16:03
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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)	30 SEP 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 16:56
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3722406

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 16:26 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 16:26

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

US3722406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	16:19 (24 HR)
Collection date and time (derived)	30 SEP 2020 16:19

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	30 SEP 2020 16:15
Nasopharyngeal Swab 2	Yes	16:15	30 SEP 2020 16:15

US3722406

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 16:51

PC Open Date & Time

30 SEP 2020 16:46

PC Close Date & Time

30 SEP 2020 19:16

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**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

96.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	30 SEP 2020 22:20
PC Open Date & Time	30 SEP 2020 20:11
PC Close Date & Time	01 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 14:15

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 15:47

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**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

97.2 °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

03 OCT 2020 13:23

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**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

97.8 °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

04 OCT 2020 18:30

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 22:05

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 02:30

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**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

30 SEP 2020 16:52

PC Open Date & Time

30 SEP 2020 16:46

PC Close Date & Time

30 SEP 2020 19:16

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**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

30 SEP 2020 22:21

PC Open Date & Time

30 SEP 2020 20:11

PC Close Date & Time

01 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

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

93

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

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

Yes ☒

No ☐

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

48

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

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

01 OCT 2020 14:20

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

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

130

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

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

Yes ☒

No ☐

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

30

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

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

02 OCT 2020 15:48

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

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

130

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

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

Yes ☐

No ☒

Please record - **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

03 OCT 2020 13:26

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

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

150

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

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

Yes ☐

No ☒

Please record - **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

04 OCT 2020 18:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

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

120

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

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

Yes ☐

No ☒

Please record - **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

05 OCT 2020 22:05

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 02:31

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 16:53
PC Open Date & Time	30 SEP 2020 16:46
PC Close Date & Time	30 SEP 2020 19:16

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 22:22
---------------	-------------------

PC Open Date & Time	30 SEP 2020 20:11
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PC Close Date & Time	01 OCT 2020 11:59
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US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**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 ☒

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 14:21
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**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)

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US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 15:49
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**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

96 of 1703

EAB) (1725)

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:26
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**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  
EAB) (1725)

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US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:31
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

100 of 1703

EAB) (1725)

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 22:06
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**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 ☐

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

		Yes <input type="checkbox"/>
PC Time stamp	07 OCT 2020 02:32	
PC Open Date & Time	06 OCT 2020 12:00	
PC Close Date & Time	07 OCT 2020 11:59	



US3722406

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 07 OCT 2020 22:34

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3722406

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:04

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	07 OCT 2020 22:34
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3722406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722406

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3722406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 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

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	15:42 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 15:42
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 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
Height (derived)	
Weight (derived)	

US3722406

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3722406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

15:59 (24 HR)

Collection date and time (derived)

12 NOV 2020 15:59

US3722406

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:40

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 NOV 2020 18:37:45
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2020 23:59

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US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 NOV 2020 08:12:22
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

**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

06 DEC 2020 08:32:28

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 DEC 2020 14:30:39
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

**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

20 DEC 2020 08:04:56

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59



US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:02:06

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3722406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

**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

03 JAN 2021 08:19:57

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

**US3722406**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:28:04**

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

US3722406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3722406

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3722406**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:04**

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*



**US3722406**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:04**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722406

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:04

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"/>

**US3722406**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:28:04**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3722406

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

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 UNBLND\_DECIDE

US3722406

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	29 DEC 2020
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3722406

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3722406

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3722406

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

AEID	USA-US083-2020-MRNA-1273-P30 1000006
Adverse event	WORSENING BENIGN PROSTATE HYPERPLASIA
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 OCT 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)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	144 of 1703

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

---

SAE REPORTED AT VISIT 3.  
SITE HAS REQUESTED  
RECORDS AND WILL UPDATE  
DETAILS ONCE RECEIVED.

SITE HAS RECEIVED RECORDS  
FROM SPECIALIST, BUT IS  
PENDING ADDITIONAL  
RECORDS. NO COVID TESTING  
WAS INCLUDED IN THE  
RECORDS. SUBJECT HAS  
MEDICAL HISTORY OF BPH,  
BUT SYMPTOMS OF URINARY  
RETENTION AND BLADDER  
SPASMS HAVE WORSENERED,  
WHICH LED TO THE SUBJECT  
GOING THROUGH WITH THE  
TURP.

10-14-2020 - HGB 11.7; 10:13-2020  
HGB 12.8; CREATININE 1.28  
10-13-2020; 10-5-20 PVR- 750 ML

---

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)	

---

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US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

AEID

Adverse event

CONSTIPATION

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)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☐

If not Ongoing, end date (dd MMM yyyy)

27 OCT 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

PRODUCTION RELEASE (v12.003

147 of 1703

EAB) (1725)

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

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	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	

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

---

SUBJECT REPORTED SAE TO  
SITE AT VISIT 3. SITE HAS  
REQUESTED MEDICAL  
RECORDS AND WILL UPDATE  
WITH DETAILS ONCE  
RECEIVED.

UPON RECEIPT AND REVIEW OF  
THE RECORDS, IT WAS  
DETERMINED THAT THIS  
EVENT WAS NOT AN SAE  
DESPITE WHAT THE SUBJECT  
INITIALLY REPORTED.  
SUBJECT DID EXPERIENCE  
CONSTIPATION AND  
HEMATURIA AND SOUGHT  
MEDICAL ATTENTION AT AN  
ER. THE FOLEY CATHETER  
WAS CHANGED, LABS DRAWN,  
ECG COMPLETED, AND  
LIDOCAIN 2% 10ML GIVEN  
ONCE. RECORDS NOTE  
SUBJECT FELT BETTER ONCE  
FOLEY CATHETER WAS  
PLACED. SUBJECT WAS NOT  
ADMITTED.

AS NOTED IN MEDICAL  
HISTORY, SUBJECT HAS BPH  
REQUIRING TURP. THE  
CONSTIPATION CAME AFTER  
THE PROCEDURE AND IS  
CONSIDERED A RISK FACTOR  
FOR THE AE.

---

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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US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

AEID

Adverse event

BLADDER SPASMS

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 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 OCT 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 (3)

Data signed: (b) (4) 28 Apr 2021 21:58:16

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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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	



US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

AEID

Adverse event

CLOT RETENTION OF URINE

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)

7 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 OCT 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 (4)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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 (5)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

AEID	
Adverse event	HEMATURIA
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)	25 OCT 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)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:58:16

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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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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 (5)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

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SUBJECT INITIALLY REPORTED  
HOSPITALIZATION FOR  
CONSTIPATION. THIS REPORT  
WAS INCONSISTENT WITH THE  
RECORDS. SUBJECT WENT TO  
ER AFTER EXPERIENCING  
CONSTIPATION FOR  
HEMATURIA. HIS FOLEY  
CATHETER WAS CHANGED  
AND SYMPTOMS GREATLY  
IMPROVED. HE WAS NOT  
ADMITTED. THE FOLLOWING  
DAY HE HAD A CYSTOSCOPY  
FOR CLOT EVACUATION WITH  
HIS SPECIALIST.

---

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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US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication TADALAFIL

Prophylaxis Yes ☐  
No ☒

Indication ED

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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 2017	
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 (2)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication BLADDER SPASMS

Dose per administration 7.5/325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 26 OCT 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 (3)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication LEVSIN SL

Prophylaxis Yes ☐  
No ☒

Indication BLADDER SPASMS

Dose per administration 0.125

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 (3)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (4)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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)		08 OCT 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 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication B COMPLEX

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (5)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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)		08 OCT 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)		_____
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 (6)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (6)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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)	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 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication FLONASE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (7)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication ANTIVERT

Prophylaxis Yes ☐  
No ☒

Indication DIZZINESS

Dose per administration 12.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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 2019
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"/>

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication XYLOCAINE 2%

Prophylaxis Yes ☐  
No ☒

Indication BHP

Dose per administration 10

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	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)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 OCT 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"/>



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

Name of Medication PFIZER VACCINE

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration .3

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:58:16

Generated On: 10 Jun 2021 09:28:04

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2021
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"/>

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 11:02:39

Generated On: 10 Jun 2021 09:28:04

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 OCT 2020	FRENCH FOLEY CATHETER PLACEMENT	Medical History	
13 OCT 2020	TURP	Adverse Event	
7 OCT 2020	ECHO	Adverse Event	
7 OCT 2020	CT HEAD WITH CONTRAST	Adverse Event	
25 OCT 2020	FOLEY CATHETER REPLACED	Adverse Event	
26 OCT 2020	CYSTOSCOPY FOR CLOT EVACUATION	Adverse Event	

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

Date of study discontinuation/completion (dd MMM yyyy) 4 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input checked="" type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

SUBJECT IS A HEALTHCARE PROFESSIONAL AND INFORMED THE SITE THAT HE TOOK THE PFIZER VACCINE. WE UNBLINDED AND HE HAD GOTTEN THE VACCINE. OFF STUDY DUE TO TAKING OTHER VACCINE.

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 ☐

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:37
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/NOV/2020 13:38
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/JAN/2021 10:36
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	10/MAR/2021 13:26
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/MAR/2021 12:26
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/MAR/2021 14:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/APR/2021 09:27
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/APR/2021 12:37
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

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Data signed: (b) (4) 28 Apr 2021 21:58:17

Generated On: 10 Jun 2021 09:28:04

SAEID	USA-US083-2020-MRNA-1273-P301000006
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	23/APR/2021 14:07
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

US3722406 (Prod: Keystone VitaLink Research - Greenville - PPDS)

**US3722406**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:28:04**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'US3722406'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:34:54

US3722406

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:03

US3722406

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:34:55

US3722406

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	28 Aug 2020 20:05:03

**US3722406**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:04**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'SCRN'	System	28 Aug 2020 20:05:03

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:34:56

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '63'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31



**US3722406**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:04**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'YEARS'	System	28 Aug 2020 20:05:31

**US3722406**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:04**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '63'	System	28 Aug 2020 20:05:49

**US3722406**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:04**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Male (M)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'I'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31



US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:31

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:49

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'Aug 2020'	System	28 Aug 2020 20:05:49

**US3722406**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:04**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '2020'	System	28 Aug 2020 20:05:49



US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
Query 'Per CDM: RE-QUERY: Protocol Version is recorded as Amendment 3, however to date there is no Amendment 3, please review and update as appropriate. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:49:17
User opened query 'Per CDM: RE-QUERY: Protocol Version is recorded as Amendment 3, however to date there is no Amendment 3, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:15:30
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:15:30
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 17:40:14
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 17:40:11
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 08:13:21
User entered 'Amendment 5 (5)'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:49

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:49

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:49

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:49

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:49

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:34:55

US3722406

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'I'	System	28 Aug 2020 20:05:58

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:28:04

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:05:58



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Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:28:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:46

US3722406

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:10:40
Data point term sent to Coder	System	28 Aug 2020 20:09:27
User entered 'erectile dysfunction'	Kayla Peay (b) (4)	28 Aug 2020 20:09:06
	(b) (4)	

US3722406

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'un UNK 2017'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:06

US3722406

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:06

**US3722406**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:06

**US3722406**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:04**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:06

US3722406

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:06

**US3722406**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'Jan 2017'	System	28 Aug 2020 20:09:06



**US3722406**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '2017'	System	28 Aug 2020 20:09:06

US3722406

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	28 Aug 2020 20:09:06

**US3722406**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	28 Aug 2020 20:09:06

US3722406

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:10:40
Data point term sent to Coder	System	28 Aug 2020 20:09:27
User entered 'sleep apnea'	Kayla Peay (b) (4)	28 Aug 2020 20:09:19

US3722406

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'un UNK 2012'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:19

US3722406

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:19

**US3722406**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:19

US3722406

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:19



US3722406

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:09:19

**US3722406**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'Jan 2012'	System	28 Aug 2020 20:09:19

**US3722406**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '2012'	System	28 Aug 2020 20:09:19

**US3722406**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	28 Aug 2020 20:09:19

**US3722406**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	28 Aug 2020 20:09:19

US3722406

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:20:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:20:04
Data point term sent to Coder	System	18 Jan 2021 13:19:11
User entered 'seasonal allergies'	Marlee Smith (b) (4)	18 Jan 2021 13:19:09

US3722406

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'un UNK 2010'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:09

**US3722406**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:19:09



US3722406

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:09

US3722406

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:19:09

US3722406

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:19:09

US3722406

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'Jan 2010'	System	18 Jan 2021 13:19:09

**US3722406**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '2010'	System	18 Jan 2021 13:19:09

**US3722406**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	18 Jan 2021 13:19:09

**US3722406**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	18 Jan 2021 13:19:09

US3722406

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:21:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:21:04
Data point term sent to Coder	System	18 Jan 2021 13:20:12
User entered 'Benign Prostate hyperplasia'	Marlee Smith (b) (4)	18 Jan 2021 13:19:27



US3722406

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'un UNK 2019'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:27

US3722406

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:27

US3722406

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:27

US3722406

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:27

US3722406

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:19:27

**US3722406**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'Jan 2019'	System	18 Jan 2021 13:19:27

**US3722406**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '2019'	System	18 Jan 2021 13:19:27

**US3722406**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	18 Jan 2021 13:19:27



**US3722406**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	18 Jan 2021 13:19:27

US3722406

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 15:42:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 15:42:04
Data point term sent to Coder	System	05 Mar 2021 15:17:02
User entered 'Dizziness'	Marlee Smith (b) (4)	05 Mar 2021 15:16:30
	(b) (4)	

US3722406

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'un UNK 2019'	Marlee Smith (b) (4)	05 Mar 2021 15:16:30

**US3722406**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Marlee Smith (b) (4) (b) (4)	05 Mar 2021 15:16:30

**US3722406**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 15:16:30

US3722406

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 15:16:30
	(b) (4)	

US3722406

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 15:16:30
	(b) (4)	

**US3722406**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'Jan 2019'	System	05 Mar 2021 15:16:30



**US3722406**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '2019'	System	05 Mar 2021 15:16:30

**US3722406**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	05 Mar 2021 15:16:30

**US3722406**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered empty.	System	05 Mar 2021 15:16:30

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '14:46'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:10:11

**US3722406**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:04**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '28 Aug 2020 14:46'	System	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '71' in	(b) (4) Kayla Peay (b) (4)	28 Aug 2020 20:10:11
DataPoint set to visible.	(b) (4) System	28 Aug 2020 20:05:58



US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '199.6' lb	(b) (4) Kayla Peay (b) (4)	28 Aug 2020 20:10:11
DataPoint set to visible.	(b) (4) System	28 Aug 2020 20:05:58

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered '27.89676'	System	28 Aug 2020 20:10:11
DataPoint set to visible.	System	28 Aug 2020 20:05:58

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'kg/m2'	System	28 Aug 2020 20:10:11
DataPoint set to visible.	System	28 Aug 2020 20:05:58

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:22
User entered '97.7' F	Kayla Peay (b) (4)	28 Aug 2020 20:10:11
	(b) (4)	

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	09 Sep 2020 18:42:22
User entered 'Oral (Oral)'	(b) (4)	
	Kayla Peay (b) (4)	28 Aug 2020 20:10:11
	(b) (4)	

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:22
User entered '75'	Kayla Peay (b) (4)	28 Aug 2020 20:10:11
	(b) (4)	

**US3722406**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:04**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'bpm'	System	28 Aug 2020 20:10:11



US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:22
User entered '17'	Kayla Peay (b) (4)	28 Aug 2020 20:10:11
	(b) (4)	

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'breaths/min'	System	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:22
User entered '132'	Kayla Peay (b) (4)	28 Aug 2020 20:10:11
	(b) (4)	

**US3722406**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:04**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'mmHg'	System	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:22
User entered '80'	Kayla Peay (b) (4)	28 Aug 2020 20:10:11
	(b) (4)	

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User entered 'mmHg'	System	28 Aug 2020 20:10:11

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30

US3722406

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30



US3722406

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:10:18

US3722406

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	(b) (4) Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:10:18

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:23



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:23

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	Sara Poff (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	Sara Poff (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'I'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:06:23

US3722406

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 20:06:43



US3722406

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	Sara Poff (b) (4)	28 Aug 2020 20:06:43

US3722406

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	28 Aug 2020 20:06:43

US3722406

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'VISIT1'	System	28 Aug 2020 20:06:43

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:14:31

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '109122'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:14:31

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 19:14:31

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:57

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:57



US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:57

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:57

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	Sara Poff (b) (4)	28 Aug 2020 20:06:57

US3722406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:04

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 07:18:33
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	10 Dec 2020 21:38:27
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	10 Dec 2020 21:38:22
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 21:53:42
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:31:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:31:27

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:31
User entered '71' in	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	09 Sep 2020 18:42:31
User entered '199.6' lb	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:31
User entered '71' in	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:31
User entered '199.6' lb	Kayla Peay (b) (4)	28 Aug 2020 20:11:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '14:46'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered '28 Aug 2020 14:46'	System	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '97.7' F	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:11:24



US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '75'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'bpm'	System	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '17'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'breaths/min'	System	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '132'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'mmHg'	System	28 Aug 2020 20:11:24

US3722406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '80'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'mmHg'	System	28 Aug 2020 20:11:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 18:42:31
User entered '71' in	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	09 Sep 2020 18:42:31
User entered '199.6' lb	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 12:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 12:20:10
User entered '16:08' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:20:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:11:24
User entered empty.	System	28 Aug 2020 20:11:24
	Kayla Peay (b) (4)	28 Aug 2020 20:11:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered '28 Aug 2020 16:08'	System	31 Aug 2020 12:20:10
User entered empty.	System	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 12:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 12:20:10
User entered '97.4' F reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:20:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:11:24
User entered empty.	System	28 Aug 2020 20:11:24
	Kayla Peay (b) (4)	28 Aug 2020 20:11:24
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 12:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 12:20:10
User entered '67' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:20:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:11:24
User entered empty.	System	28 Aug 2020 20:11:24
	Kayla Peay (b) (4)	28 Aug 2020 20:11:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'bpm'	System	31 Aug 2020 12:20:10
User entered empty.	System	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 12:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 12:20:10
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:20:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:11:24
User entered empty.	System	28 Aug 2020 20:11:24
	Kayla Peay (b) (4)	28 Aug 2020 20:11:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'breaths/min'	System	31 Aug 2020 12:20:10
User entered empty.	System	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 12:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 12:20:10
User entered '123' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:20:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:11:24
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:11:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'mmHg'	System	31 Aug 2020 12:20:10
User entered empty.	System	28 Aug 2020 20:11:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 12:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 12:20:10
User entered '83' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:20:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Aug 2020 20:11:24
User entered empty.	System	28 Aug 2020 20:11:24
	Kayla Peay (b) (4)	28 Aug 2020 20:11:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:03:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'mmHg'	System	31 Aug 2020 12:20:10
User entered empty.	System	28 Aug 2020 20:11:24

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	09 Sep 2020 18:42:37
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:31

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	09 Sep 2020 18:42:37
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:11:31

US3722406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 20:07:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Sara Poff (b) (4)	28 Aug 2020 20:07:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Sara Poff (b) (4)	28 Aug 2020 20:07:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 20:07:18



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	Sara Poff (b) (4)	28 Aug 2020 20:07:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '15:33'	Sara Poff (b) (4)	28 Aug 2020 20:07:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:07:18

US3722406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	28 Aug 2020 20:07:18

US3722406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'ONCE'	System	28 Aug 2020 20:07:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 20:07:18

US3722406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:45

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:11:45



US3722406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '15:07'	Kayla Peay (b) (4)	28 Aug 2020 20:11:45

US3722406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:50
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:04:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered '28 Aug 2020 15:07'	System	28 Aug 2020 20:11:45

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '15:03'	Kayla Peay (b) (4)	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:11:56



US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '15:03'	Kayla Peay (b) (4)	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:05:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 20:11:56

US3722406

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:06:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 20:07:31

US3722406

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:30
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:06:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'l'	System	28 Aug 2020 20:07:31

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:09:55', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '73b603c3-2fa5-458e-b3bb-d1a0f10d600b' User entered 'Yes (Y)'	System	28 Aug 2020 20:10:37
	System	28 Aug 2020 20:10:37

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:10:13', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '73b603c3-2fa5-458e-b3bb-d1a0f10d600b' User entered '97.4'	System	28 Aug 2020 20:10:37
	System	28 Aug 2020 20:10:37



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:10:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '73b603c3-2fa5-458e-b3bb-d1a0f10d600b'	System	28 Aug 2020 20:10:37
User entered 'No (N)'	System	28 Aug 2020 20:10:37

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:10:35', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '73b603c3-2fa5-458e-b3bb-d1a0f10d600b' User entered '28 Aug 2020 16:10'	System	28 Aug 2020 20:10:37
	System	28 Aug 2020 20:10:37

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 15:53'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 18:23'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:16', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f4e9e303-0952-4d22-b03c-c347fa456447'	System	29 Aug 2020 12:36:40
User entered 'Yes (Y)'	System	29 Aug 2020 12:36:40

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:26', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f4e9e303-0952-4d22-b03c-c347fa456447' User entered '97.4'	System	29 Aug 2020 12:36:40
	System	29 Aug 2020 12:36:40

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:30', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f4e9e303-0952-4d22-b03c-c347fa456447'	System	29 Aug 2020 12:36:40
User entered 'No (N)'	System	29 Aug 2020 12:36:40



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:36', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f4e9e303-0952-4d22-b03c-c347fa456447'	System	29 Aug 2020 12:36:40
User entered '29 Aug 2020 08:36'	System	29 Aug 2020 12:36:40

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 19:18'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 2'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:43:30', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd8c4ff96-b5cc-4c2b-9f0d-14d160a61d50'	System	30 Aug 2020 02:43:48
User entered 'Yes (Y)'	System	30 Aug 2020 02:43:48

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:43:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd8c4ff96-b5cc-4c2b-9f0d-14d160a61d50'	System	30 Aug 2020 02:43:48
User entered '97.3'	System	30 Aug 2020 02:43:48

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:43:41', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd8c4ff96-b5cc-4c2b-9f0d-14d160a61d50'	System	30 Aug 2020 02:43:48
User entered 'No (N)'	System	30 Aug 2020 02:43:48

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:43:47', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd8c4ff96-b5cc-4c2b-9f0d-14d160a61d50'	System	30 Aug 2020 02:43:48
User entered '29 Aug 2020 22:43'	System	30 Aug 2020 02:43:48



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 3'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:09:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '1bd8fe57-270d-4355-8fef-a23da1de1d33'	System	30 Aug 2020 16:10:17
User entered 'Yes (Y)'	System	30 Aug 2020 16:10:17

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:10:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '1bd8fe57-270d-4355-8fef-a23da1de1d33'	System	30 Aug 2020 16:10:17
User entered '97.4'	System	30 Aug 2020 16:10:17

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:10:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '1bd8fe57-270d-4355-8fef-a23da1de1d33'	System	30 Aug 2020 16:10:17
User entered 'No (N)'	System	30 Aug 2020 16:10:17

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:10:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '1bd8fe57-270d-4355-8fef-a23da1de1d33'	System	30 Aug 2020 16:10:17
User entered '30 Aug 2020 12:10'	System	30 Aug 2020 16:10:17

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:07:18



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 4'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:30:30', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'af80ee40-71c0-45ba-92f0-736af4ef7414'	System	31 Aug 2020 19:32:33
User entered 'Yes (Y)'	System	31 Aug 2020 19:32:33

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:30:36', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'af80ee40-71c0-45ba-92f0-736af4ef7414' User entered '96.8'	System	31 Aug 2020 19:32:33
	System	31 Aug 2020 19:32:33

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:30:39', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'af80ee40-71c0-45ba-92f0-736af4ef7414'	System	31 Aug 2020 19:32:33
User entered 'No (N)'	System	31 Aug 2020 19:32:33

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:30:44', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'af80ee40-71c0-45ba-92f0-736af4ef7414'	System	31 Aug 2020 19:32:33
User entered '31 Aug 2020 15:30'	System	31 Aug 2020 19:32:33

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:07:18



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 5'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:13:53', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '59c44506-88a9-45ee-87cd-b31fcf3ffbf8'	System	01 Sep 2020 16:14:08
User entered 'Yes (Y)'	System	01 Sep 2020 16:14:08

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:13:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '59c44506-88a9-45ee-87cd-b31fcf3ffb8'	System	01 Sep 2020 16:14:08
User entered '97.9'	System	01 Sep 2020 16:14:08

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:02', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '59c44506-88a9-45ee-87cd-b31fcf3ffb8'	System	01 Sep 2020 16:14:08
User entered 'No (N)'	System	01 Sep 2020 16:14:08

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '59c44506-88a9-45ee-87cd-b31fcf3ffb8'	System	01 Sep 2020 16:14:08
User entered '01 Sep 2020 12:14'	System	01 Sep 2020 16:14:08

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 6'	System	28 Aug 2020 20:07:18



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:07', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '27f3739d-2e0c-4540-bdbf-e875b9580f5f' User entered 'Yes (Y)'	System	02 Sep 2020 16:23:22
	System	02 Sep 2020 16:23:22

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '27f3739d-2e0c-4540-bdbf-e875b9580f5f' User entered '97.3'	System	02 Sep 2020 16:23:22
	System	02 Sep 2020 16:23:22

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '27f3739d-2e0c-4540-bdbf-e875b9580f5f' User entered 'No (N)'	System	02 Sep 2020 16:23:22
	System	02 Sep 2020 16:23:22

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:21', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '27f3739d-2e0c-4540-bdbf-e875b9580f5f' User entered '02 Sep 2020 12:23'	System	02 Sep 2020 16:23:22
	System	02 Sep 2020 16:23:22

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 7'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:11', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f77d4b4a-1ffa-4de0-9f5b-513abecc4f4c'	System	04 Sep 2020 05:10:25
User entered 'Yes (Y)'	System	04 Sep 2020 05:10:25



US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f77d4b4a-1ffa-4de0-9f5b-513abecc4f4c' User entered '96.7'	System	04 Sep 2020 05:10:25
	System	04 Sep 2020 05:10:25

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:20', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f77d4b4a-1ffa-4de0-9f5b-513abecc4f4c'	System	04 Sep 2020 05:10:25
User entered 'No (N)'	System	04 Sep 2020 05:10:25

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:23', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'f77d4b4a-1ffa-4de0-9f5b-513abecc4f4c'	System	04 Sep 2020 05:10:25
User entered '04 Sep 2020 01:10'	System	04 Sep 2020 05:10:25

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:11:02', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd590940e-5844-4463-bcfd-f5e8f248639f' User entered 'None (1)'	System	28 Aug 2020 20:12:13
	System	28 Aug 2020 20:12:13

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:11:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd590940e-5844-4463-bcfd-f5e8f248639f' User entered 'No (N)'	System	28 Aug 2020 20:12:13
	System	28 Aug 2020 20:12:13



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:11:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd590940e-5844-4463-bcfd-f5e8f248639f' User entered 'No (N)'	System	28 Aug 2020 20:12:13
	System	28 Aug 2020 20:12:13

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:03', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd590940e-5844-4463-bcfd-f5e8f248639f' User entered 'None (1)'	System	28 Aug 2020 20:12:13
	System	28 Aug 2020 20:12:13

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd590940e-5844-4463-bcfd-f5e8f248639f' User entered '28 Aug 2020 16:12'	System	28 Aug 2020 20:12:13
	System	28 Aug 2020 20:12:13

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 15:53'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 18:23'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:46', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '04a361c0-194a-424c-9e63-1b6cad93498f' User entered 'None (1)'	System	29 Aug 2020 12:37:03
	System	29 Aug 2020 12:37:03

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:50', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '04a361c0-194a-424c-9e63-1b6cad93498f' User entered 'No (N)'	System	29 Aug 2020 12:37:03
	System	29 Aug 2020 12:37:03



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:53', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '04a361c0-194a-424c-9e63-1b6cad93498f' User entered 'No (N)'	System	29 Aug 2020 12:37:03
	System	29 Aug 2020 12:37:03

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:36:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '04a361c0-194a-424c-9e63-1b6cad93498f' User entered 'None (1)'	System	29 Aug 2020 12:37:03
	System	29 Aug 2020 12:37:03

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '04a361c0-194a-424c-9e63-1b6cad93498f' User entered '29 Aug 2020 08:37'	System	29 Aug 2020 12:37:03
	System	29 Aug 2020 12:37:03

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 19:18'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 2'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:44:23', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a13b63c4-4a98-46d0-b658-9e13292b3a8e'	System	30 Aug 2020 02:45:12
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 02:45:12

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:44:26', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a13b63c4-4a98-46d0-b658-9e13292b3a8e' User entered 'No (N)'	System	30 Aug 2020 02:45:12
	System	30 Aug 2020 02:45:12



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:44:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a13b63c4-4a98-46d0-b658-9e13292b3a8e' User entered 'No (N)'	System	30 Aug 2020 02:45:12
	System	30 Aug 2020 02:45:12

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:04', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a13b63c4-4a98-46d0-b658-9e13292b3a8e' User entered 'None (1)'	System	30 Aug 2020 02:45:12
	System	30 Aug 2020 02:45:12

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:08', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a13b63c4-4a98-46d0-b658-9e13292b3a8e' User entered '29 Aug 2020 22:45'	System	30 Aug 2020 02:45:12
	System	30 Aug 2020 02:45:12

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 3'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:10:38', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8948b54c-b418-4244-abb8-67a4e2cb8b2b' User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 16:11:47
	System	30 Aug 2020 16:11:47

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8948b54c-b418-4244-abb8-67a4e2cb8b2b' User entered 'No (N)'	System	30 Aug 2020 16:11:47
	System	30 Aug 2020 16:11:47



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8948b54c-b418-4244-abb8-67a4e2cb8b2b' User entered 'No (N)'	System	30 Aug 2020 16:11:47
	System	30 Aug 2020 16:11:47

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8948b54c-b418-4244-abb8-67a4e2cb8b2b' User entered 'None (1)'	System	30 Aug 2020 16:11:47
	System	30 Aug 2020 16:11:47

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8948b54c-b418-4244-abb8-67a4e2cb8b2b' User entered '30 Aug 2020 12:11'	System	30 Aug 2020 16:11:47
	System	30 Aug 2020 16:11:47

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 4'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfc33a96-143c-46fd-b0e5-e88cc09c1d85'	System	31 Aug 2020 19:32:50
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 19:32:50

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:13', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfc33a96-143c-46fd-b0e5-e88cc09c1d85'	System	31 Aug 2020 19:32:50
User entered 'No (N)'	System	31 Aug 2020 19:32:50



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:15', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfc33a96-143c-46fd-b0e5-e88cc09c1d85'	System	31 Aug 2020 19:32:50
User entered 'No (N)'	System	31 Aug 2020 19:32:50

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfc33a96-143c-46fd-b0e5-e88cc09c1d85'	System	31 Aug 2020 19:32:50
User entered 'None (1)'	System	31 Aug 2020 19:32:50

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfc33a96-143c-46fd-b0e5-e88cc09c1d85'	System	31 Aug 2020 19:32:50
User entered '31 Aug 2020 15:31'	System	31 Aug 2020 19:32:50

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 5'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:11', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ff8f8b83-23af-433a-aae7-dba0bd9dec3a'	System	01 Sep 2020 16:14:53
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 16:14:53

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:18', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ff8f8b83-23af-433a-aae7-dba0bd9dec3a'	System	01 Sep 2020 16:14:53
User entered 'No (N)'	System	01 Sep 2020 16:14:53



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:31', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ff8f8b83-23af-433a-aae7-dba0bd9dec3a'	System	01 Sep 2020 16:14:53
User entered 'No (N)'	System	01 Sep 2020 16:14:53

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ff8f8b83-23af-433a-aae7-dba0bd9dec3a'	System	01 Sep 2020 16:14:53
User entered 'None (1)'	System	01 Sep 2020 16:14:53

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:50', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ff8f8b83-23af-433a-aae7-dba0bd9dec3a'	System	01 Sep 2020 16:14:53
User entered '01 Sep 2020 12:14'	System	01 Sep 2020 16:14:53

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 6'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:40', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aa536a87-e44e-463f-b50e-0aaa299458ff'	System	02 Sep 2020 16:24:00
User entered 'None (1)'	System	02 Sep 2020 16:24:00

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aa536a87-e44e-463f-b50e-0aaa299458ff' User entered 'No (N)'	System	02 Sep 2020 16:24:00
	System	02 Sep 2020 16:24:00



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aa536a87-e44e-463f-b50e-0aaa299458ff' User entered 'No (N)'	System	02 Sep 2020 16:24:00
	System	02 Sep 2020 16:24:00

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:54', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aa536a87-e44e-463f-b50e-0aaa299458ff' User entered 'None (1)'	System	02 Sep 2020 16:24:00
	System	02 Sep 2020 16:24:00

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:23:58', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aa536a87-e44e-463f-b50e-0aaa299458ff' User entered '02 Sep 2020 12:23'	System	02 Sep 2020 16:24:00
	System	02 Sep 2020 16:24:00

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 7'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:28', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9c0bb783-6509-425d-bf7f-06a3f0866120'	System	04 Sep 2020 05:10:42
User entered 'None (1)'	System	04 Sep 2020 05:10:42

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:30', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9c0bb783-6509-425d-bf7f-06a3f0866120'	System	04 Sep 2020 05:10:42
User entered 'No (N)'	System	04 Sep 2020 05:10:42



US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9c0bb783-6509-425d-bf7f-06a3f0866120'	System	04 Sep 2020 05:10:42
User entered 'No (N)'	System	04 Sep 2020 05:10:42

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:35', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9c0bb783-6509-425d-bf7f-06a3f0866120'	System	04 Sep 2020 05:10:42
User entered 'None (1)'	System	04 Sep 2020 05:10:42

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:38', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9c0bb783-6509-425d-bf7f-06a3f0866120'	System	04 Sep 2020 05:10:42
User entered '04 Sep 2020 01:10'	System	04 Sep 2020 05:10:42

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:19', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'None (0)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:24', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'None (0)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:28', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'None (0)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:34', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'None (0)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'None (0)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:40', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'None (0)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered 'No (N)'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-28T16:12:52', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '0ae14045-3ccb-4578-811f-92e290ff3231' User entered '28 Aug 2020 16:12'	System	28 Aug 2020 20:12:55
	System	28 Aug 2020 20:12:55

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 15:53'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 18:23'	System	28 Aug 2020 20:07:18



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'None (0)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:12', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'None (0)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'None (0)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'None (0)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:20', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'None (0)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:23', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'None (0)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered 'No (N)'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T08:37:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'aca874af-e3a6-4d18-948b-33988d36eb9c' User entered '29 Aug 2020 08:37'	System	29 Aug 2020 12:37:36
	System	29 Aug 2020 12:37:36

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '28 Aug 2020 19:18'	System	28 Aug 2020 20:07:18

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 2'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered 'None (0)'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered 'None (0)'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:21', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered 'None (0)'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:24', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered 'None (0)'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered 'None (0)'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:29', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered 'None (0)'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:33', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7'	System	30 Aug 2020 02:45:42
User entered 'No (N)'	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-29T22:45:38', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd5d32574-531d-4ddb-b11d-0c27958861a7' User entered '29 Aug 2020 22:45'	System	30 Aug 2020 02:45:42
	System	30 Aug 2020 02:45:42

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 3'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:48', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered 'None (0)'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered 'None (0)'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:11:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered 'None (0)'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:12:03', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered 'None (0)'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:12:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered 'None (0)'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:12:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered 'None (0)'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:12:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42'	System	30 Aug 2020 16:12:23
User entered 'No (N)'	System	30 Aug 2020 16:12:23

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-30T12:12:20', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9b0c963a-9e31-4048-955a-60fadde88d42' User entered '30 Aug 2020 12:12'	System	30 Aug 2020 16:12:23
	System	30 Aug 2020 16:12:23

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:07:18



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 4'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038'	System	31 Aug 2020 19:32:59
User entered 'None (0)'	System	31 Aug 2020 19:32:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:40', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038'	System	31 Aug 2020 19:32:59
User entered 'None (0)'	System	31 Aug 2020 19:32:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:44', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038'	System	31 Aug 2020 19:32:59
User entered 'None (0)'	System	31 Aug 2020 19:32:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:47', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038' User entered 'None (0)'	System	31 Aug 2020 19:32:59
	System	31 Aug 2020 19:32:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:49', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038' User entered 'None (0)'	System	31 Aug 2020 19:32:59
	System	31 Aug 2020 19:32:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:52', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038'	System	31 Aug 2020 19:32:59
User entered 'None (0)'	System	31 Aug 2020 19:32:59



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:31:58', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038'	System	31 Aug 2020 19:32:59
User entered 'No (N)'	System	31 Aug 2020 19:32:59

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-08-31T15:32:04', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9464fab6-7885-49fc-a6f9-71c4a5f6a038'	System	31 Aug 2020 19:32:59
User entered '31 Aug 2020 15:32'	System	31 Aug 2020 19:32:59

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 5'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:55', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'None (0)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:14:58', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'None (0)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:15:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'None (0)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:15:04', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'None (0)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:15:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'None (0)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:15:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'None (0)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:15:15', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc' User entered 'No (N)'	System	01 Sep 2020 16:15:24
	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-01T12:15:20', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '3ab824b5-35ac-4f1d-89b2-d1791e7fb2cc'	System	01 Sep 2020 16:15:24
User entered '01 Sep 2020 12:15'	System	01 Sep 2020 16:15:24

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 6'	System	28 Aug 2020 20:07:18



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'None (0)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'None (0)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:19', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'None (0)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'None (0)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:24', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'None (0)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'None (0)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:30', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered 'No (N)'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-02T12:24:36', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bef4b9be-9142-4fca-a3e7-0de88553fc84' User entered '02 Sep 2020 12:24'	System	02 Sep 2020 16:24:39
	System	02 Sep 2020 16:24:39



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 7'	System	28 Aug 2020 20:07:18

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7' User entered 'None (0)'	System	04 Sep 2020 05:11:04
	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7' User entered 'None (0)'	System	04 Sep 2020 05:11:04
	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:47', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7' User entered 'None (0)'	System	04 Sep 2020 05:11:04
	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:49', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7' User entered 'None (0)'	System	04 Sep 2020 05:11:04
	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7' User entered 'None (0)'	System	04 Sep 2020 05:11:04
	System	04 Sep 2020 05:11:04



US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:53', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7' User entered 'None (0)'	System	04 Sep 2020 05:11:04
	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:10:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7'	System	04 Sep 2020 05:11:04
User entered 'No (N)'	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-04T01:11:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8d4e6bef-160e-49c7-93e3-889687ead4a7'	System	04 Sep 2020 05:11:04
User entered '04 Sep 2020 01:11'	System	04 Sep 2020 05:11:04

US3722406

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:07:18

**US3722406**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:47
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:06:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	12 Sep 2020 12:37:23

US3722406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:47
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:06:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '6 Sep 2020'	Kayla Peay (b) (4)	12 Sep 2020 12:37:23

US3722406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:47
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:06:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	12 Sep 2020 12:37:23



US3722406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:47
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:06:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	12 Sep 2020 12:37:23

US3722406

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:47
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	12 Sep 2020 12:37:27

US3722406

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:47
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:42
User entered 'l'	System	12 Sep 2020 12:37:27

US3722406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:33:48
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:41
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	12 Sep 2020 12:37:35

US3722406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:33:48
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:41
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '12 Sep 2020'	Kayla Peay (b) (4)	12 Sep 2020 12:37:35

US3722406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:33:48
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:41
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	12 Sep 2020 12:37:35

US3722406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:33:48
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:41
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	12 Sep 2020 12:37:35

US3722406

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:33:48
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:41
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	12 Sep 2020 12:37:39



US3722406

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:33:48
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:07:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:47:41
User entered 'l'	System	12 Sep 2020 12:37:39

**US3722406**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:25
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	23 Sep 2020 19:42:42

US3722406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:25
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '19 Sep 2020'	Kayla Peay (b) (4)	23 Sep 2020 19:42:42

US3722406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:25
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	23 Sep 2020 19:42:42

US3722406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:25
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	23 Sep 2020 19:42:42

US3722406

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:25
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	23 Sep 2020 19:42:44

US3722406

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:25
User entered 'I'	System	23 Sep 2020 19:42:44

US3722406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Sara Poff (b) (4)	30 Sep 2020 20:34:19



US3722406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Sara Poff (b) (4)	30 Sep 2020 20:34:19

US3722406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	30 Sep 2020 20:34:19

US3722406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'VISIT2'	System	30 Sep 2020 20:34:19

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '16:03'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '30 Sep 2020 16:03'	System	01 Oct 2020 12:20:34



US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '98.6' F	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '74'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'bpm'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '17'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'breaths/min'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '118'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34



US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'mmHg'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '75'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'mmHg'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '16:56'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '30 Sep 2020 16:56'	System	01 Oct 2020 12:20:34



US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '98.3' F	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '70'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'bpm'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '17'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'breaths/min'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '131'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34



US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'mmHg'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '86'	Kayla Peay (b) (4)	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'mmHg'	System	01 Oct 2020 12:20:34

US3722406

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	01 Oct 2020 12:20:44

US3722406

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Kayla Peay (b) (4)	01 Oct 2020 12:20:44

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Sara Poff (b) (4)	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Sara Poff (b) (4)	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Sara Poff (b) (4)	30 Sep 2020 20:34:40



US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Sara Poff (b) (4)	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '16:26' reason for change: Data Entry Error	Sara Poff (b) (4)	30 Sep 2020 20:49:27
User entered '16:56'	Sara Poff (b) (4)	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '30 Sep 2020 16:26'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 16:56'	System	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'ONCE'	System	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 20:34:40

US3722406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	01 Oct 2020 12:20:55



US3722406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Kayla Peay (b) (4)	01 Oct 2020 12:20:55

US3722406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '16:19'	Kayla Peay (b) (4)	01 Oct 2020 12:20:55

US3722406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '30 Sep 2020 16:19'	System	01 Oct 2020 12:20:55

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '30 Sep 2020'	Kayla Peay (b) (4)	01 Oct 2020 12:21:08

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	01 Oct 2020 12:21:08

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	01 Oct 2020 12:21:08

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '16:15'	Kayla Peay (b) (4)	01 Oct 2020 12:21:08

**US3722406**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '30 Sep 2020 16:15'	System	01 Oct 2020 12:21:08



US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	01 Oct 2020 12:21:08

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	01 Oct 2020 12:21:08

US3722406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '16:15'	Kayla Peay (b) (4)	01 Oct 2020 12:21:08

**US3722406**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '30 Sep 2020 16:15'	System	01 Oct 2020 12:21:08

US3722406

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Sara Poff (b) (4)	30 Sep 2020 20:44:51

US3722406

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:07
User entered '1'	System	30 Sep 2020 20:44:51

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:50:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '24ac92e6-c9bd-4717-a1f8-803621470c72'	System	30 Sep 2020 20:51:14
User entered 'Yes (Y)'	System	30 Sep 2020 20:51:14



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:51:03', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '24ac92e6-c9bd-4717-a1f8-803621470c72'	System	30 Sep 2020 20:51:14
User entered '98.3'	System	30 Sep 2020 20:51:14

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:51:07', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '24ac92e6-c9bd-4717-a1f8-803621470c72'	System	30 Sep 2020 20:51:14
User entered 'No (N)'	System	30 Sep 2020 20:51:14

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:51:12', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '24ac92e6-c9bd-4717-a1f8-803621470c72'	System	30 Sep 2020 20:51:14
User entered '30 Sep 2020 16:51'	System	30 Sep 2020 20:51:14

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 16:46'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 17:16'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 19:16'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 19:46'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:20:28', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a5fe7d94-5509-448e-b038-0da5854708aa' User entered 'Yes (Y)'	System	01 Oct 2020 02:20:46
	System	01 Oct 2020 02:20:46

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:20:34', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a5fe7d94-5509-448e-b038-0da5854708aa' User entered '96.7'	System	01 Oct 2020 02:20:46
	System	01 Oct 2020 02:20:46



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:20:38', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a5fe7d94-5509-448e-b038-0da5854708aa' User entered 'No (N)'	System	01 Oct 2020 02:20:46
	System	01 Oct 2020 02:20:46

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:20:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a5fe7d94-5509-448e-b038-0da5854708aa' User entered '30 Sep 2020 22:20'	System	01 Oct 2020 02:20:46
	System	01 Oct 2020 02:20:46

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 20:11'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 20:41'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 2'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:14:54', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4c236627-cbcc-408a-8961-7c6792dc25fe' User entered 'Yes (Y)'	System	01 Oct 2020 18:15:11
	System	01 Oct 2020 18:15:11

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:14:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4c236627-cbcc-408a-8961-7c6792dc25fe' User entered '98.8'	System	01 Oct 2020 18:15:11
	System	01 Oct 2020 18:15:11

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:15:02', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4c236627-cbcc-408a-8961-7c6792dc25fe' User entered 'No (N)'	System	01 Oct 2020 18:15:11
	System	01 Oct 2020 18:15:11



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:15:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4c236627-cbcc-408a-8961-7c6792dc25fe'	System	01 Oct 2020 18:15:11
User entered '01 Oct 2020 14:15'	System	01 Oct 2020 18:15:11

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 3'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:03', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '17341cc9-08ab-42ad-ab20-229354c2e407' User entered 'Yes (Y)'	System	02 Oct 2020 19:47:26
	System	02 Oct 2020 19:47:26

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:10', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '17341cc9-08ab-42ad-ab20-229354c2e407' User entered '97.9'	System	02 Oct 2020 19:47:26
	System	02 Oct 2020 19:47:26

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:15', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '17341cc9-08ab-42ad-ab20-229354c2e407'	System	02 Oct 2020 19:47:26
User entered 'No (N)'	System	02 Oct 2020 19:47:26

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '17341cc9-08ab-42ad-ab20-229354c2e407' User entered '02 Oct 2020 15:47'	System	02 Oct 2020 19:47:26
	System	02 Oct 2020 19:47:26



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 4'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:23:40', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6792c65f-8aea-475f-a217-8c63ea59ce8c' User entered 'Yes (Y)'	System	03 Oct 2020 17:23:59
	System	03 Oct 2020 17:23:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:23:46', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6792c65f-8aea-475f-a217-8c63ea59ce8c' User entered '97.2'	System	03 Oct 2020 17:23:59
	System	03 Oct 2020 17:23:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:23:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6792c65f-8aea-475f-a217-8c63ea59ce8c'	System	03 Oct 2020 17:23:59
User entered 'No (N)'	System	03 Oct 2020 17:23:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:23:55', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6792c65f-8aea-475f-a217-8c63ea59ce8c' User entered '03 Oct 2020 13:23'	System	03 Oct 2020 17:23:59
	System	03 Oct 2020 17:23:59

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 5'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:30:36', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '90d27fd6-b1d7-458d-ad41-2af76a093c06'	System	04 Oct 2020 22:30:52
User entered 'Yes (Y)'	System	04 Oct 2020 22:30:52

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:30:42', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '90d27fd6-b1d7-458d-ad41-2af76a093c06' User entered '97.8'	System	04 Oct 2020 22:30:52
	System	04 Oct 2020 22:30:52

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:30:47', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '90d27fd6-b1d7-458d-ad41-2af76a093c06'	System	04 Oct 2020 22:30:52
User entered 'No (N)'	System	04 Oct 2020 22:30:52

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:30:50', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '90d27fd6-b1d7-458d-ad41-2af76a093c06'	System	04 Oct 2020 22:30:52
User entered '04 Oct 2020 18:30'	System	04 Oct 2020 22:30:52

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 6'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '61d82ed2-b7b3-40bb-91ca-3f24b3d760e2' User entered 'Yes (Y)'	System	06 Oct 2020 02:05:24
	System	06 Oct 2020 02:05:24

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '61d82ed2-b7b3-40bb-91ca-3f24b3d760e2' User entered '97.9'	System	06 Oct 2020 02:05:24
	System	06 Oct 2020 02:05:24

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '61d82ed2-b7b3-40bb-91ca-3f24b3d760e2' User entered 'No (N)'	System	06 Oct 2020 02:05:24
	System	06 Oct 2020 02:05:24

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:21', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '61d82ed2-b7b3-40bb-91ca-3f24b3d760e2' User entered '05 Oct 2020 22:05'	System	06 Oct 2020 02:05:24
	System	06 Oct 2020 02:05:24

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 7'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:29:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'fb74f7c5-95b6-4ef3-94f3-8c03871ee342'	System	07 Oct 2020 06:30:12
User entered 'Yes (Y)'	System	07 Oct 2020 06:30:12

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:30:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'fb74f7c5-95b6-4ef3-94f3-8c03871ee342'	System	07 Oct 2020 06:30:12
User entered '97.6'	System	07 Oct 2020 06:30:12

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:30:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'fb74f7c5-95b6-4ef3-94f3-8c03871ee342'	System	07 Oct 2020 06:30:12
User entered 'No (N)'	System	07 Oct 2020 06:30:12

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:30:10', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'fb74f7c5-95b6-4ef3-94f3-8c03871ee342'	System	07 Oct 2020 06:30:12
User entered '07 Oct 2020 02:30'	System	07 Oct 2020 06:30:12

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:51:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4348742e-a237-40ac-aa52-5863d82bffa1'	System	30 Sep 2020 20:52:52
User entered 'None (1)'	System	30 Sep 2020 20:52:52



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:52:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4348742e-a237-40ac-aa52-5863d82bffa1' User entered 'No (N)'	System	30 Sep 2020 20:52:52
	System	30 Sep 2020 20:52:52

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:52:31', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4348742e-a237-40ac-aa52-5863d82bffa1' User entered 'No (N)'	System	30 Sep 2020 20:52:52
	System	30 Sep 2020 20:52:52

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:52:44', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4348742e-a237-40ac-aa52-5863d82bffa1'	System	30 Sep 2020 20:52:52
User entered 'None (1)'	System	30 Sep 2020 20:52:52

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:52:50', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4348742e-a237-40ac-aa52-5863d82bffa1' User entered '30 Sep 2020 16:52'	System	30 Sep 2020 20:52:52
	System	30 Sep 2020 20:52:52

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 16:46'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 17:16'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 19:16'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 19:46'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:08', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c1b962f5-7ea6-468e-a276-2ba5b3e15635'	System	01 Oct 2020 02:21:36
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 02:21:36



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:11', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c1b962f5-7ea6-468e-a276-2ba5b3e15635'	System	01 Oct 2020 02:21:36
User entered 'No (N)'	System	01 Oct 2020 02:21:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:15', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c1b962f5-7ea6-468e-a276-2ba5b3e15635'	System	01 Oct 2020 02:21:36
User entered 'No (N)'	System	01 Oct 2020 02:21:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c1b962f5-7ea6-468e-a276-2ba5b3e15635'	System	01 Oct 2020 02:21:36
User entered 'None (1)'	System	01 Oct 2020 02:21:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c1b962f5-7ea6-468e-a276-2ba5b3e15635' User entered '30 Sep 2020 22:21'	System	01 Oct 2020 02:21:36
	System	01 Oct 2020 02:21:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 20:11'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 20:41'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 2'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:15:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c'	System	01 Oct 2020 18:20:37
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 18:20:37



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:16:00', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c' User entered 'Yes (Y)'	System	01 Oct 2020 18:20:37
	System	01 Oct 2020 18:20:37

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:19:13', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c' User entered '93'	System	01 Oct 2020 18:20:37
	System	01 Oct 2020 18:20:37

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:19:25', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c' User entered 'Yes (Y)'	System	01 Oct 2020 18:20:37
	System	01 Oct 2020 18:20:37

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:20:18', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c' User entered '48'	System	01 Oct 2020 18:20:37
	System	01 Oct 2020 18:20:37

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:20:28', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c'	System	01 Oct 2020 18:20:37
User entered 'None (1)'	System	01 Oct 2020 18:20:37

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:20:34', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bf138fa6-ee58-498a-8a7d-1cce6c92295c' User entered '01 Oct 2020 14:20'	System	01 Oct 2020 18:20:37
	System	01 Oct 2020 18:20:37

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 3'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179'	System	02 Oct 2020 19:48:32
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 19:48:32

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:35', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179' User entered 'Yes (Y)'	System	02 Oct 2020 19:48:32
	System	02 Oct 2020 19:48:32

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:47:58', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179' User entered '130'	System	02 Oct 2020 19:48:32
	System	02 Oct 2020 19:48:32

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:02', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179'	System	02 Oct 2020 19:48:32
User entered 'Yes (Y)'	System	02 Oct 2020 19:48:32

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:08', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179' User entered '30'	System	02 Oct 2020 19:48:32
	System	02 Oct 2020 19:48:32

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179'	System	02 Oct 2020 19:48:32
User entered 'None (1)'	System	02 Oct 2020 19:48:32

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:27', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b45b7c-24d4-48cb-b7dd-b2fcbc370179' User entered '02 Oct 2020 15:48'	System	02 Oct 2020 19:48:32
	System	02 Oct 2020 19:48:32



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 4'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:24:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b8a9b3-f228-4858-aa7f-fddb83156589'	System	03 Oct 2020 17:26:09
User entered 'None (1)'	System	03 Oct 2020 17:26:09

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:24:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b8a9b3-f228-4858-aa7f-fddb83156589' User entered 'Yes (Y)'	System	03 Oct 2020 17:26:09
	System	03 Oct 2020 17:26:09

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:25:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b8a9b3-f228-4858-aa7f-fddb83156589' User entered '130'	System	03 Oct 2020 17:26:09
	System	03 Oct 2020 17:26:09

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:25:55', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b8a9b3-f228-4858-aa7f-fddb83156589' User entered 'No (N)'	System	03 Oct 2020 17:26:09
	System	03 Oct 2020 17:26:09

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:02', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b8a9b3-f228-4858-aa7f-fddb83156589'	System	03 Oct 2020 17:26:09
User entered 'None (1)'	System	03 Oct 2020 17:26:09



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:05', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '25b8a9b3-f228-4858-aa7f-fddb83156589' User entered '03 Oct 2020 13:26'	System	03 Oct 2020 17:26:09
	System	03 Oct 2020 17:26:09

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 5'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:30:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '7ff85e3c-596d-4ad9-93bc-425785ca267b' User entered 'None (1)'	System	04 Oct 2020 22:31:31
	System	04 Oct 2020 22:31:31

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:30:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '7ff85e3c-596d-4ad9-93bc-425785ca267b' User entered 'Yes (Y)'	System	04 Oct 2020 22:31:31
	System	04 Oct 2020 22:31:31

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:07', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '7ff85e3c-596d-4ad9-93bc-425785ca267b' User entered '150'	System	04 Oct 2020 22:31:31
	System	04 Oct 2020 22:31:31

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:11', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '7ff85e3c-596d-4ad9-93bc-425785ca267b' User entered 'No (N)'	System	04 Oct 2020 22:31:31
	System	04 Oct 2020 22:31:31



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:25', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '7ff85e3c-596d-4ad9-93bc-425785ca267b' User entered 'None (1)'	System	04 Oct 2020 22:31:31
	System	04 Oct 2020 22:31:31

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:29', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '7ff85e3c-596d-4ad9-93bc-425785ca267b' User entered '04 Oct 2020 18:31'	System	04 Oct 2020 22:31:31
	System	04 Oct 2020 22:31:31

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 6'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:26', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd6b23261-ae96-44cc-97b4-3943fbdeb3da' User entered 'None (1)'	System	06 Oct 2020 02:06:15
	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:29', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd6b23261-ae96-44cc-97b4-3943fbdeb3da' User entered 'Yes (Y)'	System	06 Oct 2020 02:06:15
	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:35', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd6b23261-ae96-44cc-97b4-3943fbdeb3da' User entered '120'	System	06 Oct 2020 02:06:15
	System	06 Oct 2020 02:06:15



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:38', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd6b23261-ae96-44cc-97b4-3943fbdeb3da' User entered 'No (N)'	System	06 Oct 2020 02:06:15
	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:46', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd6b23261-ae96-44cc-97b4-3943fbdeb3da' User entered 'None (1)'	System	06 Oct 2020 02:06:15
	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:49', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'd6b23261-ae96-44cc-97b4-3943fbdeb3da' User entered '05 Oct 2020 22:05'	System	06 Oct 2020 02:06:15
	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 7'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:30:31', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c3545104-dd71-44c7-954a-f7e9b02c344c' User entered 'None (1)'	System	07 Oct 2020 06:31:36
	System	07 Oct 2020 06:31:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:30:41', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c3545104-dd71-44c7-954a-f7e9b02c344c' User entered 'No (N)'	System	07 Oct 2020 06:31:36
	System	07 Oct 2020 06:31:36



US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:31:15', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c3545104-dd71-44c7-954a-f7e9b02c344c' User entered 'No (N)'	System	07 Oct 2020 06:31:36
	System	07 Oct 2020 06:31:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:31:29', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c3545104-dd71-44c7-954a-f7e9b02c344c' User entered 'None (1)'	System	07 Oct 2020 06:31:36
	System	07 Oct 2020 06:31:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:31:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c3545104-dd71-44c7-954a-f7e9b02c344c' User entered '07 Oct 2020 02:31'	System	07 Oct 2020 06:31:36
	System	07 Oct 2020 06:31:36

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:52:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered 'None (0)'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:05', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered 'None (0)'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered 'None (0)'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:11', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered 'None (0)'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered 'None (0)'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered 'None (0)'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4'	System	30 Sep 2020 20:53:27
User entered 'No (N)'	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T16:53:25', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8daf6124-1d38-43ad-abf4-182fe1f2e7f4' User entered '30 Sep 2020 16:53'	System	30 Sep 2020 20:53:27
	System	30 Sep 2020 20:53:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 16:46'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 17:16'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 19:16'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 19:46'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:39', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered 'None (0)'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:42', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered 'None (0)'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered 'None (0)'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:48', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered 'None (0)'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:50', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered 'None (0)'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:53', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered 'None (0)'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:21:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712'	System	01 Oct 2020 02:22:03
User entered 'No (N)'	System	01 Oct 2020 02:22:03



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-09-30T22:22:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '4fc86ce3-5675-4220-85e0-98e26b188712' User entered '30 Sep 2020 22:22'	System	01 Oct 2020 02:22:03
	System	01 Oct 2020 02:22:03

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '30 Sep 2020 20:11'	System	30 Sep 2020 20:49:27
User entered '30 Sep 2020 20:41'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 2'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:20:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385'	System	01 Oct 2020 18:21:35
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385' User entered 'None (0)'	System	01 Oct 2020 18:21:35
	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:07', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385'	System	01 Oct 2020 18:21:35
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:10', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385' User entered 'None (0)'	System	01 Oct 2020 18:21:35
	System	01 Oct 2020 18:21:35



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:13', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385' User entered 'None (0)'	System	01 Oct 2020 18:21:35
	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:17', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385' User entered 'None (0)'	System	01 Oct 2020 18:21:35
	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:21', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385'	System	01 Oct 2020 18:21:35
User entered 'No (N)'	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-01T14:21:29', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'e2616391-7dbf-4ac8-a702-30c740c29385' User entered '01 Oct 2020 14:21'	System	01 Oct 2020 18:21:35
	System	01 Oct 2020 18:21:35

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

**US3722406**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 3'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:35', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'No interference with activity (1)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:40', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'None (0)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:47', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'No interference with activity (1)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:50', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'None (0)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:53', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'None (0)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:48:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'None (0)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:49:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered 'No (N)'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-02T15:49:07', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '96534fcd-7d6f-40dc-badc-81390cc8831f' User entered '02 Oct 2020 15:49'	System	02 Oct 2020 19:49:10
	System	02 Oct 2020 19:49:10

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 4'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8' User entered 'None (0)'	System	03 Oct 2020 17:26:53
	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:16', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8' User entered 'None (0)'	System	03 Oct 2020 17:26:53
	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:34', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8'	System	03 Oct 2020 17:26:53
User entered 'No interference with activity (1)'	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:37', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8' User entered 'None (0)'	System	03 Oct 2020 17:26:53
	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:39', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8'	System	03 Oct 2020 17:26:53
User entered 'None (0)'	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8' User entered 'None (0)'	System	03 Oct 2020 17:26:53
	System	03 Oct 2020 17:26:53



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:46', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8'	System	03 Oct 2020 17:26:53
User entered 'No (N)'	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-03T13:26:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'becd874c-949d-4148-a433-78c0601f7cc8' User entered '03 Oct 2020 13:26'	System	03 Oct 2020 17:26:53
	System	03 Oct 2020 17:26:53

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 5'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:33', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered 'None (0)'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:36', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered 'None (0)'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:38', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered 'None (0)'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:41', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered 'None (0)'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered 'None (0)'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered 'None (0)'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:48', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27'	System	04 Oct 2020 22:31:54
User entered 'No (N)'	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-04T18:31:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'b2013b6b-6ecf-44c9-91ab-38931c308d27' User entered '04 Oct 2020 18:31'	System	04 Oct 2020 22:31:54
	System	04 Oct 2020 22:31:54

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

**US3722406**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 6'	System	30 Sep 2020 20:34:40



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:53', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'None (0)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:55', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'None (0)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'None (0)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:05:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'None (0)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:06:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'None (0)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:06:03', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'None (0)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:06:05', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered 'No (N)'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-05T22:06:11', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8ed647e2-1743-4172-9cc6-b2614e02e77d' User entered '05 Oct 2020 22:06'	System	06 Oct 2020 02:06:27
	System	06 Oct 2020 02:06:27



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

**US3722406**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	30 Sep 2020 20:34:40
User entered 'Day 7'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:31:55', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfd857d-4611-4c56-b50f-59b7865f198b' User entered 'None (0)'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfdf857d-4611-4c56-b50f-59b7865f198b' User entered 'None (0)'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:09', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfdf857d-4611-4c56-b50f-59b7865f198b' User entered 'None (0)'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:12', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfdf857d-4611-4c56-b50f-59b7865f198b' User entered 'None (0)'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:19', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfd857d-4611-4c56-b50f-59b7865f198b'	System	07 Oct 2020 06:32:55
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	07 Oct 2020 06:32:55



US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:32', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfd857d-4611-4c56-b50f-59b7865f198b' User entered 'None (0)'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:42', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfd857d-4611-4c56-b50f-59b7865f198b' User entered 'Yes (Y)'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T02:32:52', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'bfd857d-4611-4c56-b50f-59b7865f198b' User entered '07 Oct 2020 02:32'	System	07 Oct 2020 06:32:55
	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 20:34:40

US3722406

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	07 Oct 2020 06:32:55
User entered 'Day 8'	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:28:04

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T22:33:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9557ae3e-47ad-4f2f-8052-6ed32850a236' User entered 'None (0)'	System	08 Oct 2020 02:34:17
	System	08 Oct 2020 02:34:17

US3722406

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T22:34:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '9557ae3e-47ad-4f2f-8052-6ed32850a236' User entered '07 Oct 2020 22:34'	System	08 Oct 2020 02:34:17
	System	08 Oct 2020 02:34:17



US3722406

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 06:32:55

**US3722406**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 09:28:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 06:32:55

US3722406

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
DataPoint Activated.	System	07 Oct 2020 06:32:55
DataPoint Inactivated.	System	07 Oct 2020 06:31:36
Data entry locked.	System	06 Oct 2020 02:06:15
User entered 'Day 8'	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T22:34:46', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '044cc3c1-cc76-4c1d-8190-d09f124391dd'	System	08 Oct 2020 02:34:55
User entered 'Yes (Y)'	System	08 Oct 2020 02:34:55
DataPoint Activated.	System	07 Oct 2020 06:32:55
DataPoint Inactivated.	System	07 Oct 2020 06:31:36

US3722406

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-10-07T22:34:51', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '044cc3c1-cc76-4c1d-8190-d09f124391dd'	System	08 Oct 2020 02:34:55
User entered '07 Oct 2020 22:34'	System	08 Oct 2020 02:34:55
DataPoint Activated.	System	07 Oct 2020 06:32:55
DataPoint Inactivated.	System	07 Oct 2020 06:31:36

US3722406

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
DataPoint Activated.	System	07 Oct 2020 06:32:55
DataPoint Inactivated.	System	07 Oct 2020 06:31:36
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 02:06:15

US3722406

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
DataPoint Activated.	System	07 Oct 2020 06:32:55
DataPoint Inactivated.	System	07 Oct 2020 06:31:36
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 02:06:15

US3722406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Oct 2020 19:26:36



US3722406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '7 Oct 2020'	Kayla Peay (b) (4)	08 Oct 2020 19:26:36

US3722406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	08 Oct 2020 19:26:36

US3722406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Kayla Peay (b) (4)	08 Oct 2020 19:26:36

US3722406

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:07
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Oct 2020 19:26:39

US3722406

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:07
User entered 'I'	System	08 Oct 2020 19:26:39

US3722406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:10
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User closed query 'Per CDM RQ : Response noted. Please update Was contact attempted?. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:43:35
Query 'Per CDM RQ : Response noted. Please update Was contact attempted?. Thank you.' answered with 'updated' (Site from DM).	Kayla Peay (b) (4)	14 Oct 2020 18:37:57
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	14 Oct 2020 18:37:46
	(b) (4)	
User opened query 'Per CDM RQ : Response noted. Please update Was contact attempted?. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:28:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 09:26:54
Query 'Data is required. Please complete.' answered with 'entry error' (Site from System).	Taylor Wilson (b) (4)	09 Oct 2020 12:18:17
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 12:17:49
User entered empty; reason for change Data Entry Error	Taylor Wilson (b) (4)	09 Oct 2020 12:17:49
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	09 Oct 2020 12:17:26
	(b) (4)	

US3722406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:10
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '14 Oct 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	14 Oct 2020 18:37:46
	(b) (4)	
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 12:17:49
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Oct 2020 12:17:49
User entered empty; reason for change Data Entry Error	Taylor Wilson (b) (4)	09 Oct 2020 12:17:49
	(b) (4)	
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 12:17:26
User entered '09 Oct 2020'	Taylor Wilson (b) (4)	09 Oct 2020 12:17:26
	(b) (4)	

US3722406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:10
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	14 Oct 2020 18:37:46
reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Taylor Wilson (b) (4)	09 Oct 2020 12:17:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	09 Oct 2020 12:17:26
	(b) (4)	



US3722406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 13:51:10
User signature succeeded.	Luis De La Cruz (b) (4) [REDACTED] (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Taylor Wilson (b) (4) [REDACTED] (b) (4)	09 Oct 2020 12:17:26

US3722406

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:10
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Oct 2020 18:37:36
	(b) (4)	

US3722406

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:51:10
User entered '1'	System	14 Oct 2020 18:37:36

US3722406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:24
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	26 Oct 2020 16:24:05
	(b) (4)	

US3722406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:24
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '22 Oct 2020'	Kayla Peay (b) (4)	26 Oct 2020 16:24:05
	(b) (4)	

US3722406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:24
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	26 Oct 2020 16:24:05
	(b) (4)	

US3722406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:24
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	26 Oct 2020 16:24:05
	(b) (4)	

US3722406

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:24
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	16 Nov 2020 14:20:40
	(b) (4)	



US3722406

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:24
User entered 'I'	System	16 Nov 2020 14:20:40

US3722406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	16 Nov 2020 14:21:10

US3722406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 01:15:19
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Marlee Smith (b) (4)	16 Nov 2020 14:21:19
answered with 'date is correct' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Nov 2020 14:21:10
User entered '12 Nov 2020'	Marlee Smith (b) (4)	16 Nov 2020 14:21:10
	(b) (4)	

US3722406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	16 Nov 2020 14:21:10

US3722406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered 'VISIT3'	System	16 Nov 2020 14:21:10

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '12 Nov 2020'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '15:42'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43



**US3722406**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:04**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered '12 Nov 2020 15:42'	System	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '98' F	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '81'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered 'bpm'	System	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '18'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered 'breaths/min'	System	16 Nov 2020 14:21:43



US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '120'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered 'mmHg'	System	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '75'	Marlee Smith (b) (4)	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered 'mmHg'	System	16 Nov 2020 14:21:43

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47

US3722406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47

US3722406

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	16 Nov 2020 14:21:50

US3722406

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '12 Nov 2020'	Marlee Smith (b) (4)	16 Nov 2020 14:21:50



US3722406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	16 Nov 2020 14:21:58

US3722406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '12 Nov 2020'	Marlee Smith (b) (4)	16 Nov 2020 14:21:58

US3722406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '15:59'	Marlee Smith (b) (4)	16 Nov 2020 14:21:58

US3722406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered '12 Nov 2020 15:59'	System	16 Nov 2020 14:21:58

US3722406

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	16 Nov 2020 14:22:00

US3722406

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:47
User entered 'I'	System	16 Nov 2020 14:22:00

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 64'	System	28 Aug 2020 20:07:18

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[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)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

Have you been exposed to someone with 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)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30
Data entry locked.	System	28 Aug 2020 20:07:18
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 20:07:18

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30
Data entry locked.	System	28 Aug 2020 20:07:18
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 20:07:18

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 71'	System	28 Aug 2020 20:07:18

US3722406

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

Have you been exposed to someone with 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)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30
Data entry locked.	System	28 Aug 2020 20:07:18
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 20:07:18

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:08:30
Data entry locked.	System	28 Aug 2020 20:07:18
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 20:07:18

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered 'Day 78'	System	28 Aug 2020 20:07:18

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-14T18:37:04', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c6e6d7e0-5ce4-4a09-9c4e-41ecdb9da559'	System	14 Nov 2020 23:37:55
User entered 'Yes (Y)'	System	14 Nov 2020 23:37:55



US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

Have you been exposed to someone with 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)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-14T18:37:10', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c6e6d7e0-5ce4-4a09-9c4e-41ecdb9da559'	System	14 Nov 2020 23:37:55
User entered 'No (N)'	System	14 Nov 2020 23:37:55

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-14T18:37:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c6e6d7e0-5ce4-4a09-9c4e-41ecdb9da559'	System	14 Nov 2020 23:37:55
User entered 'No (N)'	System	14 Nov 2020 23:37:55

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-14T18:37:28', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c6e6d7e0-5ce4-4a09-9c4e-41ecdb9da559'	System	14 Nov 2020 23:37:55
User entered 'Yes (Y)'	System	14 Nov 2020 23:37:55

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-14T18:37:35', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c6e6d7e0-5ce4-4a09-9c4e-41ecdb9da559'	System	14 Nov 2020 23:37:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 23:37:55

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-14T18:37:45', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'c6e6d7e0-5ce4-4a09-9c4e-41ecdb9da559'	System	14 Nov 2020 23:37:55
User entered '14 Nov 2020 18:37:45'	System	14 Nov 2020 23:37:55

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 20:07:18

US3722406

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:47:28
Data entry locked.	System	28 Aug 2020 20:07:18
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 20:07:18

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-29T08:11:33', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '2eec615e-d1eb-490b-b0a7-6c66d250f2de' User entered 'No (N)'	System	29 Nov 2020 13:12:31
	System	29 Nov 2020 13:12:31

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Have you been exposed to someone with 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-29T08:12:07', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '2eec615e-d1eb-490b-b0a7-6c66d250f2de' User entered 'Yes (Y)'	System	29 Nov 2020 13:12:31
	System	29 Nov 2020 13:12:31

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Please 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-29T08:12:14', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '2eec615e-d1eb-490b-b0a7-6c66d250f2de'	System	29 Nov 2020 13:12:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 13:12:31

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-11-29T08:12:22', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '2eec615e-d1eb-490b-b0a7-6c66d250f2de' User entered '29 Nov 2020 08:12:22'	System	29 Nov 2020 13:12:31
	System	29 Nov 2020 13:12:31

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-06T08:32:13', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a3e0b032-1eda-4124-ac14-e1bbffcc5267'	System	06 Dec 2020 13:32:30
User entered 'No (N)'	System	06 Dec 2020 13:32:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Have you been exposed to someone with 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-06T08:32:23', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a3e0b032-1eda-4124-ac14-e1bbffcc5267'	System	06 Dec 2020 13:32:30
User entered 'No (N)'	System	06 Dec 2020 13:32:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-06T08:32:28', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'a3e0b032-1eda-4124-ac14-e1bbffcc5267' User entered '06 Dec 2020 08:32:28'	System	06 Dec 2020 13:32:30
	System	06 Dec 2020 13:32:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:08:30



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-15T14:30:01', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6c73f971-7bf9-4fac-8c51-76da9ebff715'	System	15 Dec 2020 19:30:47
User entered 'No (N)'	System	15 Dec 2020 19:30:47

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

Have you been exposed to someone with 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-15T14:30:23', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6c73f971-7bf9-4fac-8c51-76da9ebff715'	System	15 Dec 2020 19:30:47
User entered 'Yes (Y)'	System	15 Dec 2020 19:30:47

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Please 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-15T14:30:33', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6c73f971-7bf9-4fac-8c51-76da9ebff715'	System	15 Dec 2020 19:30:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Dec 2020 19:30:47

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-15T14:30:39', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6c73f971-7bf9-4fac-8c51-76da9ebff715'	System	15 Dec 2020 19:30:47
User entered '15 Dec 2020 14:30:39'	System	15 Dec 2020 19:30:47

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-20T08:04:34', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ca3156af-9462-497c-9e1f-1f68d26b0d5c' User entered 'No (N)'	System	20 Dec 2020 13:05:00
	System	20 Dec 2020 13:05:00



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

Have you been exposed to someone with 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-20T08:04:49', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ca3156af-9462-497c-9e1f-1f68d26b0d5c' User entered 'No (N)'	System	20 Dec 2020 13:05:00
	System	20 Dec 2020 13:05:00

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-20T08:04:56', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: 'ca3156af-9462-497c-9e1f-1f68d26b0d5c' User entered '20 Dec 2020 08:04:56'	System	20 Dec 2020 13:05:00
	System	20 Dec 2020 13:05:00

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-27T00:01:47', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8c3c93b8-972b-4180-8839-f287f6b1a25a' User entered 'No (N)'	System	27 Dec 2020 05:02:40
	System	27 Dec 2020 05:02:40

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

Have you been exposed to someone with 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-27T00:01:59', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8c3c93b8-972b-4180-8839-f287f6b1a25a' User entered 'No (N)'	System	27 Dec 2020 05:02:40
	System	27 Dec 2020 05:02:40

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2020-12-27T00:02:06', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '8c3c93b8-972b-4180-8839-f287f6b1a25a' User entered '27 Dec 2020 00:02:06'	System	27 Dec 2020 05:02:40
	System	27 Dec 2020 05:02:40



**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2021-01-03T08:19:43', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6771eed7-e281-40f1-a00e-020c0ee12115'	System	03 Jan 2021 13:20:01
User entered 'No (N)'	System	03 Jan 2021 13:20:01

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Have you been exposed to someone with 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 (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2021-01-03T08:19:52', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6771eed7-e281-40f1-a00e-020c0ee12115'	System	03 Jan 2021 13:20:01
User entered 'No (N)'	System	03 Jan 2021 13:20:01

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B97AC90D-0905-4145-A1F7-7A4D34EA9A4E)', Time: '2021-01-03T08:19:57', User OID: 'PatientReportedOutcome (US3722406)', ODM File OID: '6771eed7-e281-40f1-a00e-020c0ee12115'	System	03 Jan 2021 13:20:01
User entered '03 Jan 2021 08:19:57'	System	03 Jan 2021 13:20:01

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:08:30

**US3722406**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:08:30
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:08:30



US3722406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	23 Nov 2020 20:13:03

US3722406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '23 Nov 2020'	Marlee Smith (b) (4)	23 Nov 2020 20:13:03

US3722406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	23 Nov 2020 20:13:03

**US3722406**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:04**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Marlee Smith (b) (4)	23 Nov 2020 20:13:03

US3722406

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	23 Nov 2020 20:13:46

**US3722406**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:07:40
User entered 'I'	System	23 Nov 2020 20:13:46

**US3722406**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:02:12
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	29 Dec 2020 15:31:18

US3722406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:02:12
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '29 Dec 2020'	Taylor Wilson (b) (4)	29 Dec 2020 15:31:18



US3722406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:02:12
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	29 Dec 2020 15:31:18

US3722406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:02:12
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Taylor Wilson (b) (4)	29 Dec 2020 15:31:18

US3722406

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:02:12
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	29 Dec 2020 15:31:26

**US3722406**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:04**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:02:12
User entered 'I'	System	29 Dec 2020 15:31:26

US3722406

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

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	31 Mar 2021 14:42:18
	(b) (4)	

US3722406

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

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:42:18
	(b) (4)	

US3722406

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

Form: Visit Date

Generated On: 10 Jun 2021 09:28:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:42:18
	(b) (4)	

**US3722406**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:04**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 14:42:18



US3722406

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'I'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

US3722406

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

**US3722406**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:04**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'Amendment 5 (Amendment 5)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

US3722406

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User closed query 'Per Sponsor Review: Per IRT, subject was unblinded on 29DEC2020. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:00:00
Query 'Per Sponsor Review: Per IRT, subject was unblinded on 29DEC2020. Please review and reconcile.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	08 Apr 2021 13:29:50
User entered '29 Dec 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	08 Apr 2021 13:29:46
User opened query 'Per Sponsor Review: Per IRT, subject was unblinded on 29DEC2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:20:32
User entered '4 Mar 2021'	Marlee Smith (b) (4) (b) (4)	31 Mar 2021 14:43:21

US3722406

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

US3722406

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

US3722406

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	



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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:21
	(b) (4)	

**US3722406**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:04**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:43:21

**US3722406**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:04**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:43:21

US3722406

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:25
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:43:25
	(b) (4)	

**US3722406**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:04**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:43:25
	(b) (4)	

**US3722406**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:04**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:43:25

US3722406

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:04**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	31 Mar 2021 14:43:28
	(b) (4)	



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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:43:28
	(b) (4)	

**US3722406**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:04**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	31 Mar 2021 14:43:28
	(b) (4)	

**US3722406**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:04**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 14:43:28

US3722406

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:28:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:47:13
User closed query 'Per DM CLR: Medical Attention was checked for DAY 8 on Diary Dose 2. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:31:29
Query 'Per DM CLR: Medical Attention was checked for DAY 8 on Diary Dose 2. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' answered with 'No AE. Subject checked in regards to annual check up' (Site from DM).	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 13:40:01

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:28:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Medical Attention was checked for DAY 8 on Diary Dose 2. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF with "Was this a medically-attended AE?" = YES. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	20 Apr 2021 01:23:55
	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:17
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:44
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:32
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:25
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:34:55
User entered 'USA-US083-2020-mRNA-1273-P301000006'	System	16 Nov 2020 14:33:05
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 14:33:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:29:58
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:01:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:01:53
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Benign Prostate Hyperplasia. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:10:31
Data point term sent to Coder	System	10 Mar 2021 21:58:21
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Benign Prostate Hyperplasia. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Updated term' (Site from DM).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:57:51
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:57:39
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:57:39
User entered 'Worsening Benign Prostate Hyperplasia' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:57:39
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Benign Prostate Hyperplasia. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:03:03
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:42
User closed query 'PV Query: Please update event term for BPH leading to TURP to include just the underlying diagnosis and not the procedure (i.e. BPH or worsening BPH).' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:35:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:41:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:41:57
Query 'PV Query: Please update event term for BPH leading to TURP to include just the underlying diagnosis and not the procedure (i.e. BPH or worsening BPH).' answered with 'Updated ' (Site from Safety).	Sara Poff (b) (4)	24 Nov 2020 20:41:14
Data point term sent to Coder	System	24 Nov 2020 20:40:58
Coding entries removed.	Sara Poff (b) (4)	24 Nov 2020 20:40:04
User entered 'BPH' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Nov 2020 20:40:04
User opened query 'PV Query: Please update event term for BPH leading to TURP to include just the underlying diagnosis and not the procedure (i.e. BPH or worsening BPH).' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:32:31
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:07:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:07:33
Data point term sent to Coder	System	13 Nov 2020 19:12:36
User entered 'BPH leading to TURP'	Kayla Peay (b) (4)	13 Nov 2020 19:11:51



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:30:02
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 19:47:30
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:52:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:52:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:56
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:51
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:05:17
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:59
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:22:02
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (08 Oct 2020). If not updating the start date, please clarify' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:43:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:28:58
Query ' PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (08 Oct 2020). If not updating the start date, please clarify' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 20:14:38
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 20:14:19
User entered '08 Oct 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 20:14:19
User opened query ' PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (08 Oct 2020). If not updating the start date, please clarify' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:49:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:40:35
User closed query 'Per CDM Re-query: Please complete Start date, Ongoing?, If not Ongoing, end date and Hospitalization details once medical records are available. Keep query open until changes have been made. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:34:08
Query 'Per CDM Re-query: Please complete Start date, Ongoing?, If not Ongoing, end date and Hospitalization details once medical records are available. Keep query open until changes have been made. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:52:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Jan 2021 15:52:05
User opened query 'Per CDM Re-query: Please complete Start date, Ongoing?, If not Ongoing, end date and Hospitalization details once medical records are available. Keep query open until changes have been made. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:04:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:02:30
Query 'Data is required. Please complete.' answered with 'Medical records requested, will complete once received. ' (Site from System).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:11:51
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:30:09
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (08 Oct 2020). If not updating the start date, please clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:21:55
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (08 Oct 2020). If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 13:53:15
User entered empty.	System	13 Nov 2020 19:11:51

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:30:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:02:33
Query 'Data is required. Please complete.' answered with 'Medical records requested, will complete once received.' (Site from System).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:16
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:11:51
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User closed query 'Per CRIO, end date is 14Oct20. Please confirm if 13 or 14Oct and ensure CRIO and EDC are both accurate.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:52:51
Query 'Per CRIO, end date is 14Oct20. Please confirm if 13 or 14Oct and ensure CRIO and EDC are both accurate.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:52:50
DataPoint Un-verified.	Marlee Smith (b) (4)	07 Apr 2021 17:21:48
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 17:21:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:21:34
User opened query 'Per CRIO, end date is 14Oct20. Please confirm if 13 or 14Oct and ensure CRIO and EDC are both accurate.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:48:38
Query 'Please verify if end date should be 14Oct20.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:46:14
User opened query 'Please verify if end date should be 14Oct20.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:36:28
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:32:19
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Marlee Smith (b) (4)	09 Jan 2021 15:52:05
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'Medical records requested, will complete once received.' (Site from System).	(b) (4)	25 Nov 2020 06:02:38
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Sara Poff (b) (4)	24 Nov 2020 20:40:19
User entered empty.	(b) (4)	13 Nov 2020 19:11:51
	Kayla Peay (b) (4)	13 Nov 2020 19:11:51

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:04**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:30:15
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:04**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:11:51

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

Severity

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:31:51
User closed query 'PV Query: Please confirm intensity of grade 3 as event resulted in hospitalization, and consider upgrading. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:00
Query 'PV Query: Please confirm intensity of grade 3 as event resulted in hospitalization, and consider upgrading. ' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	24 Nov 2020 17:32:08
User opened query 'PV Query: Please confirm intensity of grade 3 as event resulted in hospitalization, and consider upgrading. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:33:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:41:26
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:41:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:41:32
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:41:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 10:10:14
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Updated' (Site from System).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:58:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Mar 2021 21:57:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:02:47
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Medical records requested, will complete once received. ' (Site from System).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:30
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:11:51
User entered 'I'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 15:41:42
User closed query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:09:44
Query 'PV Query: Please provide the hospital admission date.' answered with 'Updated' (Site from Safety).	Kayla Peay (b) (4)	10 Mar 2021 21:58:13
	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	10 Mar 2021 21:57:39
	(b) (4)	
User opened query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:46:11
User closed query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:03
Query 'PV Query: Please provide the hospital admission date.' answered with 'Medical records requested, will complete once received.' (Site from Safety).	Sara Poff (b) (4)	24 Nov 2020 20:40:33
	(b) (4)	
User opened query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:29:51
User entered empty.	Kayla Peay (b) (4)	13 Nov 2020 19:11:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:41:45
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:09:49
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:58:15
User entered '14 Oct 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 21:57:39
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:46:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:05
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Medical records requested, will complete once received.' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:36
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:30:01
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:38:03
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:38:00
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:56
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:55
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:51
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51



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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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:49
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:47
User closed query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 15:36:11
Query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' answered with 'updated' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:52:27
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:52:05
User opened query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:47:05
User closed query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:08
Query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' answered with 'Medical records requested, will complete once received.' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:40
User opened query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:31:24
User entered 'None (NONE)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:04**

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:30
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded procedure of TURP that match this AE. Please verify if the recorded procedure was performed for this AE. If yes, update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:54:07
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:54:01
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded procedure of TURP that match this AE. Please verify if the recorded procedure was performed for this AE. If yes, update accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:53:37
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:53:31
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:53:22
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded procedure of TURP that match this AE. Please verify if the recorded procedure was performed for this AE. If yes, update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:04:03

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None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 10:47:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Nov 2020 20:41:26
User entered '1' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Nov 2020 20:41:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	13 Nov 2020 19:11:51
User entered '0'	System	13 Nov 2020 19:11:51
	Kayla Peay (b) (4)	13 Nov 2020 19:11:51
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:38
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:37:09
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Mar 2021 20:53:22
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	13 Nov 2020 19:11:51
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:37:02
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'IQVIA Medical query: Please provide details regarding concomitant medication Pfizer vaccine administered in 2021, considering that subject received 2 doses of vaccine in study. ' answered with 'Pfizer vaccine is included in Con Meds. Please clarify what additional information is required. Thanks. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	04 May 2021 01:58:23
User opened query 'IQVIA Medical query: Please provide details regarding concomitant medication Pfizer vaccine administered in 2021, considering that subject received 2 doses of vaccine in study. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:37:19
User signature succeeded.	Luis De La Cruz (b) (4) (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:36:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Updated ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 13:37:46
User entered 'SAE REPORTED AT VISIT 3. SITE HAS REQUESTED RECORDS AND WILL UPDATE DETAILS ONCE RECEIVED.	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 13:37:23
SITE HAS RECEIVED RECORDS FROM SPECIALIST, BUT IS PENDING ADDITIONAL RECORDS. NO COVID TESTING WAS INCLUDED IN THE RECORDS. SUBJECT HAS MEDICAL HISTORY OF BPH, BUT SYMPTOMS OF URINARY RETENTION AND BLADDER SPASMS HAVE WORSENERED, WHICH LED TO THE SUBJECT GOING THROUGH WITH THE TURP.		
10-14-2020 - HGB 11.7; 10-13-2020 HGB 12.8; CREATININE 1.28 10-13-2020; 10-5-20 PVR- 750 ML' reason for change: Data Entry Error		
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 13:36:54

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SAE REPORTED AT VISIT 3. SITE HAS REQUESTED RECORDS AND WILL UPDATE DETAILS ONCE RECEIVED.  SITE HAS RECEIVED RECORDS FROM SPECIALIST, BUT IS PENDING ADDITIONAL RECORDS. NO COVID TESTING WAS INCLUDED IN THE RECORDS. SUBJECT HAS MEDICAL HISTORY OF BPH, BUT SYMPTOMS OF URINARY RETENTION AND BLADDER SPASMS HAVE WORSENER, WHICH LED TO THE SUBJECT GOING THROUGH WITH THE TURP. 10-14-2020 - HGB 11.7; 10-13-2020 HGB 12.8; Creatinine 1.28 10-13-2020; 10-5-20 PVR- 750 ml; 11-4-20 PVR - 41 ml' reason for change: Data Entry Error DataPoint Verified.	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 13:36:54
	(b) (4), (b) (6)	07 Apr 2021 15:45:04
User closed query 'PV Query: Please provide signs and symptoms exhibited by the subject' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:10:05
User closed query 'PV Query: Please confirm if the subject had a history of BPH (prior to onset of study) or if this was a new diagnosis. If considered MH, please add to MH eCRF' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:10:02
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)	11 Mar 2021 17:09:57
Query 'PV Query: Please provide signs and symptoms exhibited by the subject' answered with 'Updated' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 22:06:23
Query 'PV Query: Please confirm if the subject had a history of BPH (prior to onset of study) or if this was a new diagnosis. If considered MH, please add to MH eCRF' answered with 'Yes, BPH is med hx. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 22:06:10

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**Form: Adverse Events (1)**

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[Narrative](#)

Audit	User	Time (GMT)
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 'No COVID testing in records. Note made.' (Site from Safety).	Kayla Peay (b) (4)	10 Mar 2021 22:05:58
User entered 'SAE REPORTED AT VISIT 3. SITE HAS REQUESTED RECORDS AND WILL UPDATE DETAILS ONCE RECEIVED.'	Kayla Peay (b) (4)	10 Mar 2021 21:57:39
Site has received records from specialist, but is pending additional records. No COVID testing was included in the records. Subject has medical history of BPH, but symptoms of urinary retention and bladder spasms have worsened, which led to the subject going through with the TURP.' reason for change: Data Entry Error		
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)	10 Mar 2021 18:23:20
User closed query 'PV Query: Please clarify if treatment for event BPH included TURP.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 18:23:14
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 'updated' (Site from Safety).	Marlee Smith (b) (4)	09 Mar 2021 20:53:55
Query 'PV Query: Please clarify if treatment for event BPH included TURP.' answered with 'confirmed' (Site from Safety).	Marlee Smith (b) (4)	09 Mar 2021 20:53:47

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:54:29
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. (issue for both events)' canceled (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:54:24
User opened query 'PV Query: Please clarify if treatment for event BPH included TURP.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:51:11
User opened query 'PV Query: Please provide signs and symptoms exhibited by the subject' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:50:31
User opened query 'PV Query: Please confirm if the subject had a history of BPH (prior to onset of study) or if this was a new diagnosis. If considered MH, please add to MH eCRF' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:49:50
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 Dec 2020 16:49:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:48:44

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
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. (issue for both events)' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:48:30
User closed query 'PV Query: Please provide signs and symptoms exhibited by the subject ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:23
User closed query 'PV Query: Please confirm if the subject had a history of BPH (prior to onset of study) or if this was a new diagnosis. If considered MH, please add to MH eCRF' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:13
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)	25 Nov 2020 13:36:11
Query 'PV Query: Please provide signs and symptoms exhibited by the subject ' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:41:04
Query 'PV Query: Please confirm if the subject had a history of BPH (prior to onset of study) or if this was a new diagnosis. If considered MH, please add to MH eCRF' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:41:01

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
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 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:56
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 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:40:52
User opened query 'PV Query: Please provide signs and symptoms exhibited by the subject ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 13:33:06
User opened query 'PV Query: Please confirm if the subject had a history of BPH (prior to onset of study) or if this was a new diagnosis. If considered MH, please add to MH eCRF' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 13:32:48
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) (b) (4), (b) (6)	23 Nov 2020 13:32:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 13:31:58

US3722406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 13:31:47
User entered 'SAE reported at Visit 3. Site has requested records and will update details once received.'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:11:51

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:11:51



**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Jan 2021 15:52:05
User entered '0'	System	13 Nov 2020 19:11:51

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:16:36
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:16:31
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Mar 2021 19:16:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:33
User entered 'USA-US083-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	16 Nov 2020 14:35:45

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Condition not present in CRIO. Please note that this condition overlaps with BPH, but admission to the hospital is for one or the other as the principal reason. Please review and place the condition that was not the cause for hospitalization as an AE, not an SAE' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 16:38:14
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 14:02:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 14:02:56
Data point term sent to Coder	System	11 Mar 2021 14:01:59
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 14:01:56
User entered 'CONSTIPATION' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 14:01:56
Query 'Condition not present in CRIO. Please note that this condition overlaps with BPH, but admission to the hospital is for one or the other as the principal reason. Please review and place the condition that was not the cause for hospitalization as an AE, not an SAE' answered with 'This was initially reported based on subject's report and was actually a different visit to the ER. Once records were received, site confirmed this did not meet the criteria for an SAE. ' (Site from CRA).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 22:08:36
User opened query 'Condition not present in CRIO. Please note that this condition overlaps with BPH, but admission to the hospital is for one or the other as the principal reason. Please review and place the condition that was not the cause for hospitalization as an AE, not an SAE' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 16:38:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 23:21:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 23:21:41
Data point term sent to Coder	System	13 Nov 2020 19:13:40
User entered 'Severe Constipation'	Kayla Peay (b) (4)	13 Nov 2020 19:13:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 19:54:52
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:53:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:53:29
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:05:28
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Per CDM Re-query: Please complete Start date, Ongoing?, If not Ongoing, end date and Hospitalization details once medical records are available. Keep query open until changes have been made. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:35:20
Query 'Per CDM Re-query: Please complete Start date, Ongoing?, If not Ongoing, end date and Hospitalization details once medical records are available. Keep query open until changes have been made. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:53:39
User entered '24 Oct 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:53:29
User opened query 'Per CDM Re-query: Please complete Start date, Ongoing?, If not Ongoing, end date and Hospitalization details once medical records are available. Keep query open until changes have been made. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:05:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:05:13
Query 'Data is required. Please complete.' answered with 'Medical records requested, will complete once received.' (Site from System).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:41:46
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:13:29
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User entered empty.	System	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:05:15
Query 'Data is required. Please complete.' answered with 'Medical records requested, will complete once received.' (Site from System).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:59
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:42:50
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:50
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '27 Oct 2020' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Jan 2021 15:53:29
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:05:20
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 20:42:50
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'Medical records requested, will complete once received.' (Site from System).	Sara Poff (b) (4)	24 Nov 2020 20:41:49
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		13 Nov 2020 19:13:29
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	13 Nov 2020 19:13:29
User entered empty.	Kayla Peay (b) (4)	13 Nov 2020 19:13:29

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:04**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:04**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User entered empty.	System	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'PV Query: Please confirm intensity of grade 2 as event resulted in hospitalization, and consider upgrading. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:08:53
Query 'PV Query: Please confirm intensity of grade 2 as event resulted in hospitalization, and consider upgrading. ' answered with 'Subject went to ER but was not hospitalized. Initially reported based of subject's report, but upon receiving records, the information is updated to be accurate. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 15:38:46
User opened query 'PV Query: Please confirm intensity of grade 2 as event resulted in hospitalization, and consider upgrading. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:56:00
User closed query 'PV Query: Please confirm intensity of grade 2 as event resulted in hospitalization, and consider upgrading. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:32
Query 'PV Query: Please confirm intensity of grade 2 as event resulted in hospitalization, and consider upgrading. ' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:41:52
User opened query 'PV Query: Please confirm intensity of grade 2 as event resulted in hospitalization, and consider upgrading. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:36:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Mar 2021 13:55:52
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	10 Mar 2021 22:09:46
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 22:09:46
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29



**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Mar 2021 13:55:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:05:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Medical records requested, will complete once received.' (Site from System).	Sara Poff (b) (4)	24 Nov 2020 20:41:56
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:13:29
User entered '1'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:08:42
Query 'PV Query: Please provide the hospital admission date.' answered with 'No hospitalization ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 13:56:47
User opened query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:52:47
User closed query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:37
Query 'PV Query: Please provide the hospital admission date.' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:41:59
User opened query 'PV Query: Please provide the hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:34:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:08:49
Query 'Please provide the hospital discharge date when available.' answered with 'No hospitalization ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 13:56:57
User opened query 'Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:53:05
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:45
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:02
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:34:18
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29



US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 15:36:29
Query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' answered with 'updated' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:53:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:53:29
User opened query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:53:22
User closed query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:36:49
Query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' answered with 'Medical records requested, will complete once received.' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:07
User opened query 'PV Query: If onset date was after 30 Sep 2020, please update action taken to not applicable. If events occurred prior to this date, please state correct as reported or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:35:00
User entered 'None (NONE)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 09:45:54
Query 'Per DM CLR: Please note that there is no Con Kayla Peay Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'No treatment or procedure completed to resolve the constipation directly. ' (Site from DM).	(b) (4) (b) (4)	11 Mar 2021 15:40:06
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 10:47:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Nov 2020 20:42:29
User entered '1' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Nov 2020 20:42:29
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	13 Nov 2020 19:13:29
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:59
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:09:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:09:01
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)	11 Mar 2021 17:08:58
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Updated narrative. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 15:45:37

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED SAE TO SITE AT VISIT 3. SITE HAS REQUESTED MEDICAL RECORDS AND WILL UPDATE WITH DETAILS ONCE RECEIVED.  UPON RECEIPT AND REVIEW OF THE RECORDS, IT WAS DETERMINED THAT THIS EVENT WAS NOT AN SAE DESPITE WHAT THE SUBJECT INITIALLY REPORTED. SUBJECT DID EXPERIENCE CONSTIPATION AND HEMATURIA AND SOUGHT MEDICAL ATTENTION AT AN ER. THE FOLEY CATHETER WAS CHANGED, LABS DRAWN, ECG COMPLETED, AND LIDOCAIN 2% 10ML GIVEN ONCE. RECORDS NOTE SUBJECT FELT BETTER ONCE FOLEY CATHETER WAS PLACED. SUBJECT WAS NOT ADMITTED.  As noted in Medical History, subject has BPH requiring TURP. The constipation came after the procedure and is considered a risk factor for the AE.' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Mar 2021 15:45:26
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'None relevant to this AE.' (Site from Safety).	Kayla Peay (b) (4)	11 Mar 2021 15:43:02
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'No treatment given directly for constipation. ' (Site from Safety).	Kayla Peay (b) (4)	11 Mar 2021 15:42:48

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED SAE TO SITE AT VISIT 3. SITE HAS REQUESTED MEDICAL RECORDS AND WILL UPDATE WITH DETAILS ONCE RECEIVED.  UPON RECEIPT AND REVIEW OF THE RECORDS, IT WAS DETERMINED THAT THIS EVENT WAS NOT AN SAE DESPITE WHAT THE SUBJECT INITIALLY REPORTED. SUBJECT DID EXPERIENCE CONSTIPATION AND HEMATURIA and sought medical attention at an ER. The Foley catheter was changed, labs drawn, ECG completed, and Lidocain 2% 10ml given once. Records note subject felt better once Foley catheter was placed. Subject was not admitted.' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Mar 2021 15:41:57
User entered 'SUBJECT REPORTED SAE TO SITE AT VISIT 3. SITE HAS REQUESTED MEDICAL RECORDS AND WILL UPDATE WITH DETAILS ONCE RECEIVED.	Kayla Peay (b) (4)	11 Mar 2021 14:01:56
Upon receipt and review of the records, it was determined that this event was not an SAE despite what the subject initially reported. Subject did experience constipation and hematuria.' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:55:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:55:06
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:53:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:37:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:37:02
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)	25 Nov 2020 13:37:00
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:14
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 'Medical records requested, will complete once received. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 20:42:11
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:35:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:35:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 13:35:13
User entered 'Subject reported SAE to site at Visit 3. Site has requested medical records and will update with details once received.'	Kayla Peay (b) (4) (b) (4)	13 Nov 2020 19:13:29

US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User entered '0'	System	10 Mar 2021 22:09:46
User entered '1'	System	13 Nov 2020 19:13:29



US3722406

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47
User entered '1'	System	09 Jan 2021 15:53:29
User entered '0'	System	13 Nov 2020 19:13:29

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:47

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Bladder spasm, LLT: Bladder spasm - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:25:04
Data point term sent to Coder	System	18 Jan 2021 13:24:13
User entered 'Bladder Spasms'	Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

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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)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '08 Oct 2020'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55



**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User entered empty.	System	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User closed query 'Please review and determine the end date as 13Oct2020, appears this may have been ongoing a little longer.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:39:19
Query 'Please review and determine the end date as 13Oct2020, appears this may have been ongoing a little longer.' answered with 'Updated' (Site from CRA).	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:11:04
User entered '26 Oct 2020' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:10:57
User opened query 'Please review and determine the end date as 13Oct2020, appears this may have been ongoing a little longer.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 21:01:55
User entered '13 Oct 2020'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User entered empty.	System	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55



**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:23:55



US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'None (NONE)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	17 Mar 2021 12:47:43
User entered '0'	(b) (4)	
	Marlee Smith (b) (4)	18 Jan 2021 13:23:55
	(b) (4)	

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'I'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55



US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marlee Smith (b) (4)	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:23:55

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User entered '0'	System	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51
User entered 'I'	System	18 Jan 2021 13:23:55

US3722406

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:04

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:51

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Haemorrhage urinary tract, LLT: Blood clot in urine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Jan 2021 11:11:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 11:11:22
Data point term sent to Coder	System	18 Jan 2021 13:25:13
User entered 'Clot retention of urine'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:24:58



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '7 Oct 2020'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User entered empty.	System	18 Jan 2021 13:24:58

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '14 Oct 2020'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User entered empty.	System	18 Jan 2021 13:24:58

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58



US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58
	(b) (4)	

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58



**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'None (NONE)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '0'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'I'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User entered '0'	System	18 Jan 2021 13:24:58



US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57
User entered 'I'	System	18 Jan 2021 13:24:58

US3722406

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:04

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:57

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:21:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:21:51
Data point term sent to Coder	System	11 Mar 2021 16:21:03
User entered 'Hematuria'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '25 Oct 2020'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11



**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User entered empty.	System	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 16:21:34
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:21:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 16:20:11
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '26 Oct 2020'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User entered empty.	System	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11



US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11



US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'None (NONE)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered '0'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
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)	06 Apr 2021 17:25:07
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 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 13:58:47
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 13:58:43
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) (4), (b) (6)	27 Mar 2021 02:23:16
User entered '1'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'l'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11



US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:49:28
User entered empty.	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User closed query 'Per DM CLR: Narrative = HAD A CYSTOSCOPY FOR CLOT EVACUATION . 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) (4), (b) (6)	12 Apr 2021 12:53:30
Query 'Per DM CLR: Narrative = HAD A CYSTOSCOPY FOR CLOT EVACUATION . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 19:04:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:49:28
User opened query 'Per DM CLR: Narrative = HAD A CYSTOSCOPY FOR CLOT EVACUATION . 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)	27 Mar 2021 02:23:25
User entered 'Subject initially reported hospitalization for constipation. This report was inconsistent with the records. Subject went to ER after experiencing constipation for hematuria. His Foley Catheter was changed and symptoms greatly improved. He was not admitted. The following day he had a cystoscopy for clot evacuation with his specialist.'	Kayla Peay (b) (4) (b) (4)	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User entered '0'	System	11 Mar 2021 16:20:11

**US3722406**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01
User entered 'I'	System	11 Mar 2021 16:20:11

US3722406

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:04

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:01

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:54:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User closed query 'Per CDM: Per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:47:29
' (Site from DM). Query 'Per CDM: Per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.'	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 20:09:57
' answered with 'updated' (Site from DM). User opened query 'Per CDM: Per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.'	(b) (4), (b) (6)	06 Apr 2021 17:16:53
' (Site from DM). User closed query 'Per medical records received, Xylocaine 2% 10ml injection was administered in ER on 25Oct2020. If confirmed, please update con meds.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 16:39:36
Query 'Per medical records received, Xylocaine 2% 10ml injection was administered in ER on 25Oct2020. If confirmed, please update con meds.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:28:01
User opened query 'Per medical records received, Xylocaine 2% 10ml injection was administered in ER on 25Oct2020. If confirmed, please update con meds.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:10:10
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:05

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 12:06:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 12:06:36
Data point term sent to Coder	System	28 Aug 2020 20:09:27
User entered 'tadalafil'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'ed'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered '5'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'un UNK 2017'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered '0'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered empty.	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:16:42
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:08:31

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:08:31



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:08:31

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:12:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:12:04
Data point term sent to Coder	System	18 Jan 2021 13:11:01
User entered 'Norco'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Bladder Spasms'	Marlee Smith (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '7.5/325'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'mg (mg)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'as needed (PRN)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (ORAL)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '08 Oct 2020'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:57:57
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)	22 Mar 2021 14:20:00
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 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:47:15
Signature has been broken.	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:47:04
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:47:04
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 Mar 2021 06:18:05
User signature succeeded.	Luis De La Cruz (b) (4) (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:57:57
Signature has been broken.	Marlee Smith (b) (4)	17 Mar 2021 12:47:04
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4) Marlee Smith (b) (4)	17 Mar 2021 12:47:04
User signature succeeded.	(b) (4) Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:57:57
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:56:26
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	01 Mar 2021 16:12:26
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	01 Mar 2021 16:12:21
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 13:01:02
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:10:27



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
User entered empty.	System	18 Jan 2021 13:10:27

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
User entered empty.	System	18 Jan 2021 13:10:27

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:59
User entered empty.	System	18 Jan 2021 13:10:27

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:36
User closed query 'Per DM CLR : Please review "Other Action Taken" field for AE #3 in AE eCRF as it does not reflect this indication for Con Meds #2 and 3. Please reconcile and correct response in AE eCRF as appropriate. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:20:22
Query 'Per DM CLR : Please review "Other Action Taken" field for AE #3 in AE eCRF as it does not reflect this indication for Con Meds #2 and 3. Please reconcile and correct response in AE eCRF as appropriate. Otherwise, provide comment. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:47:28
User opened query 'Per DM CLR : Please review "Other Action Taken" field for AE #3 in AE eCRF as it does not reflect this indication for Con Meds #2 and 3. Please reconcile and correct response in AE eCRF as appropriate. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:19:49
User signature succeeded.	Luis De La Cruz (b) (4) (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE SULFATE, PRODUCTSYNONYM: LEVSIN SL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:13:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:13:04
Data point term sent to Coder	System	18 Jan 2021 13:12:02
User entered 'Levsin SL'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:43
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:45
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Bladder Spasms'	Marlee Smith (b) (4)	18 Jan 2021 13:11:20

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:48
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0.125'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:50
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'mg (mg)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:20



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'three times daily (TID)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Oral (ORAL)'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '08 Oct 2020'	(b) (4) Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:15
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)	22 Mar 2021 14:20:20
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 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:49:32
Signature has been broken.	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:49:27
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 12:49:27
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 Mar 2021 06:18:56
User signature succeeded.	Luis De La Cruz (b) (4) (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:15
Signature has been broken.	Marlee Smith (b) (4)	17 Mar 2021 12:49:27
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4) Marlee Smith (b) (4)	17 Mar 2021 12:49:27
User signature succeeded.	(b) (4) Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	(b) (4) Marlee Smith (b) (4)	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:15
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:56:34
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	01 Mar 2021 16:12:37
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	01 Mar 2021 16:12:32
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 13:02:32
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:20

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
User entered '3'	System	18 Jan 2021 13:11:20

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
User entered '1'	System	18 Jan 2021 13:11:20

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:36:00
User entered '804 (804)'	System	18 Jan 2021 13:11:20

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Jan 2021 13:13:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:13:04
Data point term sent to Coder	System	18 Jan 2021 13:12:02
User entered 'Vitamin C'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:11:52

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Supplement'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '1000'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'mg (mg)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'once daily (QD)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '08 Oct 2020'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:11:52
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:11:52

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:11:52

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Jan 2021 13:11:52

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Jan 2021 13:14:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:14:09
Data point term sent to Coder	System	18 Jan 2021 13:13:02
User entered 'B complex'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:12:29



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'supplement'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '100'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'mg (mg)'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'as needed (PRN)'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '08 Oct 2020'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:12:29
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 13:12:29

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 13:12:29



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 13:12:29

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Jan 2021 13:30:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:30:04
Data point term sent to Coder	System	18 Jan 2021 13:14:10
User entered 'Zyrtec'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:13:04

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'seasonal allergies'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '10'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'mg (mg)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'once daily (QD)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'un UNK 2010'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:04
	(b) (4)	



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:13:04

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:13:04

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Jan 2021 13:13:04

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Mar 2021 16:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 16:13:50
Data point term sent to Coder	System	01 Mar 2021 16:13:10
Coding entries removed.	Marlee Smith (b) (4)	01 Mar 2021 16:13:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Feb 2021 19:36:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 19:36:02
Data point term sent to Coder	System	05 Feb 2021 12:51:44
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' canceled (Site from System).	Coder Import (b) (4)	05 Feb 2021 12:51:13
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	03 Feb 2021 10:21:15

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:15:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 13:15:04
Data point term sent to Coder	System	18 Jan 2021 13:14:10
User entered 'Flonase'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:13:50

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'seasonal allergies'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '100'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'ug (ug)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'once daily (QD)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Per DM CLR: Please review Route field if NASAL SPRAY is more appropriate route for this medication. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:47:34
Query 'Per DM CLR: Please review Route field if NASAL SPRAY is more appropriate route for this medication. Update as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	01 Mar 2021 16:13:15
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	01 Mar 2021 16:13:09
User opened query 'Per DM CLR: Please review Route field if NASAL SPRAY is more appropriate route for this medication. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 14:16:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:13:50

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'un UNK 2010'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:13:50
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:13:50

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:13:50

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Jan 2021 13:13:50

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE HYDROCHLORIDE, PRODUCTSYNONYM: ANTIVERT [MECLOZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Jan 2021 14:57:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 14:57:06
Data point term sent to Coder	System	18 Jan 2021 13:15:11
User entered 'antivert'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:15:03

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
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)	05 Mar 2021 17:03:11
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 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 15:16:10
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)	28 Feb 2021 16:20:47
User entered 'dizziness'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:15:03

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '12.5'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'mg (mg)'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'twice daily (BID)'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'un UNK 2019'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered '0'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:04

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	18 Jan 2021 13:15:03
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Jan 2021 13:15:03

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 13:15:03

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Jan 2021 13:15:03



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: XYLOCAINE [LIDOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:54:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:54:58
Data point term sent to Coder	System	11 Mar 2021 18:58:19
Data point term sent to Coder	System	09 Mar 2021 20:30:24
User entered 'Xylocaine 2%'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:04**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'BHP'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered '10'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered empty.	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'once (ONCE)'	Marlee Smith (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered empty.	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Marlee Smith (b) (4)	11 Mar 2021 18:58:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered empty.	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered '25 Oct 2020'	Marlee Smith (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered '0'	Marlee Smith (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

**US3722406**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:04**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered '25 Oct 2020'	Marlee Smith (b) (4)	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:10:42
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:29:37

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User entered empty.	System	09 Mar 2021 20:29:37



US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User entered empty.	System	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:54
User entered empty.	System	09 Mar 2021 20:29:37

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 20:14:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 20:14:30
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 20:10:49
User entered 'pfizer vaccine'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'Yes (Y)'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'vaccine'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
	(b) (4)	
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
User closed query 'Per CDM: If the dose is unknown, it should be recorded as "UNK". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 15:16:26
Query 'Per CDM: If the dose is unknown, it should be recorded as "UNK". Please update accordingly.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	12 Apr 2021 13:26:47
DataPoint Un-verified.	(b) (4)	
	Marlee Smith (b) (4)	12 Apr 2021 13:26:43
User entered '3' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	12 Apr 2021 13:26:43
User opened query 'Per CDM: If the dose is unknown, it should be recorded as "UNK". Please update accordingly.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 03:22:44
	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 13:47:20
Query 'Data is required. Please complete.' answered with 'dose unknown' (Site from System).	Marlee Smith (b) (4)	06 Apr 2021 20:10:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Apr 2021 20:10:39
	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Un-verified.	Marlee Smith (b) (4)	12 Apr 2021 13:26:43
	(b) (4)	
User entered 'mL (mL)' reason for change: Data Entry Error	Marlee Smith (b) (4)	12 Apr 2021 13:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 13:47:22
Query 'Data is required. Please complete.' answered with 'dose unit unknown' (Site from System).	Marlee Smith (b) (4)	06 Apr 2021 20:10:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:10:39
User entered empty.	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered empty.	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	



US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'once (ONCE)'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered empty.	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered empty.	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered empty.	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'I'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'No (N)'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'UN UNK 2021'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:10:49
User entered 'No (N)'	Marlee Smith (b) (4)	06 Apr 2021 20:10:39
	(b) (4)	

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User entered empty.	System	06 Apr 2021 20:10:39

US3722406

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User entered empty.	System	06 Apr 2021 20:10:39

US3722406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:40
User entered empty.	System	06 Apr 2021 20:10:39

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:28:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:48:19
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	18 Jan 2021 13:17:16
User entered 'No (N)'	(b) (4)	
	Kayla Peay (b) (4)	28 Aug 2020 20:08:41
	(b) (4)	

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered '7 Oct 2020'	Marlee Smith (b) (4)	18 Jan 2021 13:17:44
	(b) (4)	

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'French Foley Catheter Placement'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:17:44

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'Medical History (MH)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:17:44



US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:04

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:17:44

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered '13 Oct 2020'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:02

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'TURP'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:02

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:02

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:30
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:02

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:33
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered '7 Oct 2020'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:15

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:33
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'ECHO'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:15

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:33
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:15



US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:33
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:15

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered '7 Oct 2020'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:30

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'CT head with contrast'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:30

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:30

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:58:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	18 Jan 2021 13:18:30

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '25 Oct 2020'	Marlee Smith (b) (4)	11 Mar 2021 18:53:09

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:28:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Foley catheter replaced'	Marlee Smith (b) (4)	11 Mar 2021 18:53:09

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	11 Mar 2021 18:53:09



US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:28:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	Marlee Smith (b) (4)	11 Mar 2021 18:53:09

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:28:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '26 Oct 2020'	Marlee Smith (b) (4)	07 Apr 2021 19:04:48

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:28:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'CYSTOSCOPY FOR CLOT EVACUATION'	Marlee Smith (b) (4)	07 Apr 2021 19:04:48

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:28:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	07 Apr 2021 19:04:48

US3722406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:28:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:33:43
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered empty.	Marlee Smith (b) (4)	07 Apr 2021 19:04:48

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User closed query 'Per CDM: Please fill the Dosing Discontinuation form details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:57:41
Query 'Per CDM: Please fill the Dosing Discontinuation form details. Thank you.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	09 Jan 2021 15:49:22
User opened query 'Per CDM: Please fill the Dosing Discontinuation form details. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:56:26
User entered '4 Jan 2021'	Sara Poff (b) (4) (b) (4)	04 Jan 2021 22:06:13

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User closed query 'Per CDM: Per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:17:22
Query 'Per CDM: Per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	06 Apr 2021 20:09:50
Signature has been broken.	Marlee Smith (b) (4)	06 Apr 2021 20:09:44
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Marlee Smith (b) (4)	06 Apr 2021 20:09:44
User opened query 'Per CDM: Per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Sara Poff (b) (4)	04 Jan 2021 22:06:13

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'Subject is a healthcare professional and informed the site that he took the Pfizer vaccine. We unblinded and he had gotten the vaccine. Off study due to taking other vaccine.'	Sara Poff (b) (4)	04 Jan 2021 22:06:13



US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Sara Poff (b) (4)	04 Jan 2021 22:06:13

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered empty.	Sara Poff (b) (4)	04 Jan 2021 22:06:13

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Sara Poff (b) (4)	04 Jan 2021 22:06:13
	(b) (4)	

US3722406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:04

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:29:09
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
	(b) (4)	
User entered empty.	Sara Poff (b) (4)	04 Jan 2021 22:06:13
	(b) (4)	

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
User entered '16/Nov/2020 09:37'	System	16 Nov 2020 14:37:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
User entered '19/Nov/2020 13:05'	System	19 Nov 2020 18:05:55

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:37:49
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 18:05:55



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
User entered '25/Nov/2020 13:38'	System	25 Nov 2020 13:38:03

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:36:49
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 19:51:01
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 13:38:03

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:46:52
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered '11/Jan/2021 10:36'	(b) (4) System	11 Jan 2021 15:36:57

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:28:04

**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)	07 Apr 2021 15:46:52
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 18:25:27
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:36:57

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:46:52
User entered '10/Mar/2021 13:26'	System	10 Mar 2021 18:26:26

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:46:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 17:11:30
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 18:26:26

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:46:52
User entered '11/Mar/2021 12:26'	System	11 Mar 2021 17:26:18

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:46:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:16:55
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 17:26:18



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:46:52
User entered '11/Mar/2021 14:17'	System	11 Mar 2021 19:17:04

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:04
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:46:52
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 19:17:04

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05



US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '08/Apr/2021 09:27'	(b) (4) System	08 Apr 2021 13:27:42

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:04
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 13:27:42

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '19/Apr/2021 12:37'	(b) (4) System	19 Apr 2021 16:37:20

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:04
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 16:37:20

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'USA-US083-2020-MRNA-1273-P301000006'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Yes (Y)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'No (N)'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Luis'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'De La Cruz'	System	16 Nov 2020 14:33:05



**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '2 Roper Corners Cir'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'Greenville'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered 'SC'	System	16 Nov 2020 14:33:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:36:56
User entered '29615'	System	16 Nov 2020 14:33:05

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:08:03
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:02:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:51:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:34
User entered 'US'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:04**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	23 Apr 2021 18:07:19
User entered '9'	System	19 Apr 2021 16:37:20
User entered '8'	System	08 Apr 2021 13:27:42
User entered '7'	System	11 Mar 2021 19:17:04
User entered '6'	System	11 Mar 2021 17:26:18
User entered '5'	System	10 Mar 2021 18:26:26
User entered '4'	System	11 Jan 2021 15:36:57
User entered '3'	System	25 Nov 2020 13:38:03
User entered '2'	System	19 Nov 2020 18:05:55
User entered '1'	System	16 Nov 2020 14:37:05

**US3722406**

**Folder: SAE USA-US083-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (11)**

**Generated On: 10 Jun 2021 09:28:04**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered '23/Apr/2021 14:07'	(b) (4) System	23 Apr 2021 18:07:19

US3722406

Folder: SAE USA-US083-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:28:04

**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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:58:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:07:19