

US3892033 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:20:41

All time stamps listed in this document are displayed in GMT

US3892033

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 17:49:50

Generated On: 10 Jun 2021 10:20:41

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[Participant ID](#)

US3892033

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

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US3892033

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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 17:49:52

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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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 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
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 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
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 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
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 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	URINARY RETENTION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	CHRONIC LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	CHRONIC RIGHT SHOULDER PAIN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	DISPLACED CLAVICAL (RIGHT)
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	HEARING LOSS (BILATERAL)
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	INTERMITTENT ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Condition	HISTORY OPIOID DEPENDENCE
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:30
Height (xxx.x)	182 cm
Weight (xxx.x)	97.2 kg
BMI (xxx.x)	29.34428 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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 17:49:52

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 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 17:49:52

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 17:49:52

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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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	True
<b>Specify</b>	DRUG STORE, BOOK STORE, GROCERY STORE, LIBRARY (HAS LIMITED HOURS)

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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 17:49:52

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What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 189144

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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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)	31 AUG 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:30
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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)	31 AUG 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:49
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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 17:49:52

Generated On: 10 Jun 2021 10:20:41

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) 31 AUG 2020

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

Treatment Date and Time (derived) 31 AUG 2020 13:59

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 17:49:52

Generated On: 10 Jun 2021 10:20:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	13:35 (24 HR)
Collection date and time (derived)	31 AUG 2020 13:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	31 AUG 2020 13:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

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 10:20:41

**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

97.7 °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

31 AUG 2020 14:45

PC Open Date & Time

31 AUG 2020 14:19

PC Close Date & Time

31 AUG 2020 16:49

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**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 96.4 °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	31 AUG 2020 19:52
PC Open Date & Time	31 AUG 2020 17:44
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**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 96.9 °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):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 SEP 2020 12:23

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	02 SEP 2020 12:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**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

96.2 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

03 SEP 2020 14:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	04 SEP 2020 12:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	06 SEP 2020 10:45
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 06:19

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 14:47

PC Open Date & Time

31 AUG 2020 14:19

PC Close Date & Time

31 AUG 2020 16:49

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**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

31 AUG 2020 19:53

PC Open Date & Time

31 AUG 2020 17:44

PC Close Date & Time

01 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**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

01 SEP 2020 12:24

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**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

02 SEP 2020 12:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**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

03 SEP 2020 14:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**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

04 SEP 2020 12:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**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

06 SEP 2020 10:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 06:20

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**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 ☐

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 14:46
PC Open Date & Time	31 AUG 2020 14:19
PC Close Date & Time	31 AUG 2020 16:49

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**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 ☐



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 19:52
PC Open Date & Time	31 AUG 2020 17:44
PC Close Date & Time	01 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:24
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

55 of 2502

EAB) (1725)

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:07
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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 ☒

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:33
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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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US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:53
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

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EAB) (1725)

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 10:53
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2502

EAB) (1725)

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 06:23
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

07 SEP 2020 12:18

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

08 SEP 2020 13:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:20:41

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

---

PC Time Stamp

---

PC Open Date & Time

09 SEP 2020 12:00

---

PC Close Date & Time

10 SEP 2020 11:59

---



US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp

10 SEP 2020 19:47

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:19

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 13:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 10:20:41

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

10 SEP 2020 19:47

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

---

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:20:41

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	07 SEP 2020 12:20
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:20:41

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 SEP 2020 13:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:20:41

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:20:41

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 19:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:20:41

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

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:20:41

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3892033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

CRC CALLED, EMAILED AND  
TEXTED SUBJECT REGARDING  
SAFETY CALL. SUBJECT IS  
UNREACHABLE. PI WAS ABLE  
TO GET A HOLD OF SUBJECT.

US3892033

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3892033

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892033

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

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 SEP 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:42
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:02
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3892033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

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 SEP 2020

What was the treatment time? (00:00-23:59) 11:30 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:30

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

What was the frequency of the study treatment dosing? ONCE

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



US3892033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

11:29 (24 HR)

Collection date and time (derived)

28 SEP 2020 11:29

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	28 SEP 2020 11:05
Nasopharyngeal Swab 2	No		

US3892033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:52

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:04

PC Open Date & Time

28 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**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

97.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	29 SEP 2020 08:47
PC Open Date & Time	28 SEP 2020 15:15
PC Close Date & Time	29 SEP 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**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

95.6 °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

29 SEP 2020 12:04

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:59

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**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

95.7 °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

02 OCT 2020 13:34

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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**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

95.7 °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

03 OCT 2020 12:36

---

PC Open Date & Time

03 OCT 2020 12:00

---

PC Close Date & Time

04 OCT 2020 11:59

---

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**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

95.6 °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

04 OCT 2020 12:49

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 12:05

PC Open Date & Time

28 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 08:47

PC Open Date & Time

28 SEP 2020 15:15

PC Close Date & Time

29 SEP 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**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 SEP 2020 12:05

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**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 SEP 2020 12:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**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

01 OCT 2020 13:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**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

02 OCT 2020 13:34

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**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

03 OCT 2020 12:36

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**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 OCT 2020 12:49

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**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 ☐

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:06
PC Open Date & Time	28 SEP 2020 11:50
PC Close Date & Time	28 SEP 2020 14:20

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**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 ☐

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 08:48
PC Open Date & Time	28 SEP 2020 15:15
PC Close Date & Time	29 SEP 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**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 ☒



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:06
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**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

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EAB) (1725)

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:05
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

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EAB) (1725)

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 13:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

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EAB) (1725)

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 13:35
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

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EAB) (1725)



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:37
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:50
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3892033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892033

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892033

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3892033

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:57
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3892033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

11:26 (24 HR)

Collection date and time (derived)

26 OCT 2020 11:26

US3892033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:53

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 08:10:25

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 01:16:34

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59



US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 01:14:40

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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°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"/>

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 09:39:33

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3892033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892033

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892033

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3892033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892033

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

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*

**US3892033**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3892033

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:20:41

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"/>

**US3892033**

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

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

**Generated On: 10 Jun 2021 10:20:41**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3892033

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:20:41

Date of updated informed consent ( <i>dd MMM yyyy</i> )	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	27 JAN 2021
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	

US3892033

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 17:49:50

Generated On: 10 Jun 2021 10:20:41

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3892033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID	USA-US209-2020-MRNA-1273-P30 1000002
Adverse event	SUBARACHNOID HEMORRHAGE
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)	20 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	22 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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US3892033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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

US3892033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

---

SUBJECT CONTACTED FOR  
MONTHLY SAFETY CALL  
TODAY AND HE REPORTED HE  
IS AT REHABILITATION  
CENTER CURRENTLY. HE  
REPORTS FALLING ON  
ICE/SNOW WHILE GOING TO A  
CHURCH ACTIVITY ON 20 DEC.  
2020. HE WAS EVALUATED AT  
HOSPITAL ADMITTED AND  
TRANSFERRED TO REHAB  
'FACILITY' LATER IN THE WEEK  
WHERE HE REMAINS. HE  
ANTICIPATES POSSIBLE  
DISCHARGE HOME TOMORROW  
(29 DEC. 2020). HE DID NOT  
HAVE MANY DETAILS  
REGARDING HIS CONDITION  
OR TREATMENT ONLY THAT  
HE HAD STARTED "LORTAB".  
HE ASKED DR. ADAMS TO  
REQUEST RECORDS TO LEARN  
MORE HE DENIES ANY ILLNESS  
OR COVID-19 SINCE LAST  
STUDY CONTACT.

---

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)	

---

US3892033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID

Adverse event

LEFT CLAVICULAR FRACTURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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

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EAB) (1725)

US3892033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID

Adverse event

CHRONIC KIDNEY DISEASE  
STAGE III

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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

US3892033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID

Adverse event

RIGHT LEG HEMATOMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

179 of 2502

EAB) (1725)



US3892033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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

US3892033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

---

LEG HEMATOMA OCCURRED  
DUE TO TRAUMA BUT DID NOT  
LEAD TO OR PROLONG  
HOSPITALIZATION.  
SUBJECT REPORTS THAT THE  
HEMATOMA IS HEALING.  
CHANGED END DATE TO  
INCLUDE COMPLICATION OF  
HEMATOMA PER SPONSOR  
QUERY. WOUND HAD NOT  
RESOLVED AT TIME OF EARLY  
TERMINATION.

---

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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US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID	
Adverse event	THYROID NODULE
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)	20 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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) 12 Apr 2021 16:25:48

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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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (6)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID

Adverse event

LEFT SCALP SUBCUTANEOUS  
HEMATOMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Apr 2021 16:25:48

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

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID

Adverse event

FALL FROM GROUND LEVEL

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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	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	SUBJECT WAS TRANSPORTED TO EMERGENCY ROOM AFTER FALL. THE FALL ITSELF DID NOT LEAD TO OR PROLONG HOSPITALIZATION.
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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 (9)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	01 SEP 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)	09 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

AEID

Adverse event

HEADACHE

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)

01 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 SEP 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 (10)

Data signed: (b) (4) 12 Apr 2021 16:25:48

Generated On: 10 Jun 2021 10:20:41

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 checked="" 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 17:49:50

Generated On: 10 Jun 2021 10:20:41

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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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US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication CARVEDIOLOL

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 2014	
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 (3)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication FINASTERIDE

Prophylaxis Yes ☐  
No ☒

Indication URINARY RETENTION

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 (3)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 2014	
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"/>

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication CYMBALTA

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

Dose per administration 60

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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EAB) (1725)

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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"/>

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication ISOSORBIDE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 30

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) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Mar 2021 16:20:56

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Name of Medication POTASSIUM

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 10

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

If dose unit is Other, specify MEQ

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) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 2014	
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) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication EXCEDRIN (ACETAMINOPHEN,  
ASPIRIN AND CAFFEINE)

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED  
OSTEOARTHRITIS

Dose per administration 250-250-65

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
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 (8)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 1985	
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 (9)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication AMIODARONE

Prophylaxis Yes ☐  
No ☒

Indication INTERMITTENT ATRIAL  
FIBRILLATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Mar 2021 16:20:56

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication FATIGUE

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication LORTAB

Prophylaxis Yes ☐  
No ☒

Indication SUBARACHNOID  
HEMORRHAGE

Dose per administration 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication AMIODARONE

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILATION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication THYROID NODULE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication LEFT CLAVICULAR FRACTURE

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 (18)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication ZOFRAN

Prophylaxis Yes ☒  
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication MELATONIN

Prophylaxis Yes ☒  
No ☐

Indication INSOMNIA PROPHYLAXIS

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 (21)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication DOCUSATE

Prophylaxis Yes ☒  
No ☐

Indication BOWEL PROPHYLAXIS

Dose per administration 283

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 (22)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 checked="" 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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication BISOCODYL

Prophylaxis Yes ☒  
No ☐

Indication BOWEL PROPHYLAXIS

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 (23)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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 checked="" 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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

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 (24)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication L CLAVICLE FRACTURE

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 (25)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication PFIZER MRNA COVID-19  
VACCINE

Prophylaxis Yes ☒  
No ☐

Indication COVID-19 PREVENTION

Dose per administration 0.3

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intraocular	<input type="radio"/>
	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)		06 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 JAN 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"/>

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication LORTAB (HYDROCODONE  
BITARTRATE AND  
ACETAMINOPHEN)

Prophylaxis Yes ☐  
No ☒

Indication LEFT CLAVICULAR FRACTURE

Dose per administration 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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

245 of 2502

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT CLAVICLE FRACTURE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

247 of 2502

EAB) (1725)

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	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)	23 DEC 2020	
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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

Name of Medication ASPERCREME WITH LIDOCAINE  
4%

Prophylaxis Yes ☐  
No ☒

Indication LEFT CLAVICLE FRACTURE

Dose per administration 1

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

249 of 2502

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Mar 2021 16:20:56

Generated On: 10 Jun 2021 10:20:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 DEC 2020	CT BRAIN	Adverse Event	
20 DEC 2020	SHOULDER X-RAY LEFT	Adverse Event	
20 DEC 2020	CT BRAIN	Adverse Event	
20 DEC 2020	X-RAY TIBIA/FIBULA (RIGHT)	Adverse Event	
20 DEC 2020	CT SPINE CERVICAL WITHOUT CONTRAST	Diagnostic	
20 DEC 2020	X-RAY PELVIS	Diagnostic	
20 DEC 2020	CHEST X-RAY	Adverse Event	
21 DEC 2020	DEBRIDEMENT R LEG HEMATOMA	Adverse Event	

US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 09 Mar 2021 17:49:51

Generated On: 10 Jun 2021 10:20:41

Date of study discontinuation/completion (dd MMM yyyy) 27 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 RECEIVED OUTSIDE  
EUA VACCINE (PFIZER MRNA  
LNP-S)

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

\_\_\_\_\_

\_\_\_\_\_

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/DEC/2020 11:42
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

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/DEC/2020 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/JAN/2021 14:11
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

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/FEB/2021 10:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/FEB/2021 11:32
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



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Mar 2021 17:42:28

Generated On: 10 Jun 2021 10:20:41

SAEID	USA-US209-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/MAR/2021 11:09
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

US3892033 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

**US3892033**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 10:20:41**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'US3892033'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:32

US3892033

Form: Participant Creation

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:11

US3892033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:33

US3892033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:11

**US3892033**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:20:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'SCRN'	System	31 Aug 2020 19:18:11



US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:34

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '73'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

**US3892033**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:20:41**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'YEARS'	System	31 Aug 2020 19:18:27

**US3892033**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:20:41**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '73'	System	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27



US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

**US3892033**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:20:41**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

**US3892033**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:20:41**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:27

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:52



US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Aug 2020'	System	31 Aug 2020 19:18:52

**US3892033**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2020'	System	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:52

US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:29:33



US3892033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	31 Aug 2020 19:18:59

US3892033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:18:59

US3892033

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:20:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:19:16

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:09:32
User closed query 'Per CDM: Re-Query: Response noted. However please consider updating the indication in Concomitant medication page log # 4. Indication was mentioned as BIPOLAR for the Name of Medication CYMBALTA. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:04:29
Query 'Per CDM: Re-Query: Response noted. However please consider updating the indication in Concomitant medication page log # 4. Indication was mentioned as BIPOLAR for the Name of Medication CYMBALTA. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	22 Oct 2020 21:17:44
User opened query 'Per CDM: Re-Query: Response noted. However please consider updating the indication in Concomitant medication page log # 4. Indication was mentioned as BIPOLAR for the Name of Medication CYMBALTA. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:06:32
User closed query 'Per CDM: Please specify verbatim term ( bipolar disorder, bipolar affective, bipolar aphosis). ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:06:32
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:08:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 17:08:52
Data point term sent to Coder	System	30 Sep 2020 17:08:19
Query 'Per CDM: Please specify verbatim term ( bipolar disorder, bipolar affective, bipolar aphosis). ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	30 Sep 2020 17:07:57
Coding entries removed.	Andryelle Toledo (b) (4)	30 Sep 2020 17:07:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
User entered 'bipolar disorder' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	30 Sep 2020 17:07:36
User opened query 'Per CDM: Please specify verbatim term ( bipolar disorder, bipolar affective, bipolar aphosis). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 08:24:29
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:20:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:20:40
Data point term sent to Coder	System	01 Sep 2020 00:20:11
User entered 'bipolar'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:35
User entered 'un UNK 1990'	chase Carnahan (b) (4)	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:42
User entered '0'	chase Carnahan (b) (4)	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:39
User entered 'Yes (Y)'	chase Carnahan (b) (4)	01 Sep 2020 00:19:36



US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:44
User entered empty.	chase Carnahan (b) (4)	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:46
User entered '0'	chase Carnahan (b) (4)	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 1990'	System	01 Sep 2020 00:19:36

**US3892033**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1990'	System	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:19:36

**US3892033**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:19:36

US3892033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:13:00
Data point term sent to Coder	System	25 Feb 2021 19:11:48
Coding entries removed.	Andryelle Toledo (b) (4)	25 Feb 2021 19:11:12
User entered 'HEART FAILURE' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 19:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 22:10:01
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:52
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:20:41
Data point term sent to Coder	System	01 Sep 2020 00:20:11
User entered 'congestive heart failure'	chase Carnahan (b) (4)	01 Sep 2020 00:19:50

US3892033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 22:10:03
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:54
User entered 'un UNK 2014'	chase Carnahan (b) (4)	01 Sep 2020 00:19:50



US3892033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:09:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:09:56
User entered '0'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:19:50

**US3892033**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:19:50

US3892033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:19:50

US3892033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:19:50

US3892033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2014'	System	01 Sep 2020 00:19:50

**US3892033**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2014'	System	01 Sep 2020 00:19:50

**US3892033**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:19:50

**US3892033**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:19:50



US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:20:41
Data point term sent to Coder	System	01 Sep 2020 00:20:12
User entered 'osteoarthritis'	chase Carnahan (b) (4)	01 Sep 2020 00:20:02

US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2018'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:02

**US3892033**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:02

US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:02

US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:02

US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:02

US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2018'	System	01 Sep 2020 00:20:02

**US3892033**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2018'	System	01 Sep 2020 00:20:02



US3892033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:20:02

**US3892033**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:20:02

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:21:41
Data point term sent to Coder	System	01 Sep 2020 00:21:12
User entered 'headaches'	chase Carnahan (b) (4)	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 1985'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:19

**US3892033**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:20:19



US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 1985'	System	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1985'	System	01 Sep 2020 00:20:19

**US3892033**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:20:19

US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:21:41
Data point term sent to Coder	System	01 Sep 2020 00:21:13
User entered 'urinary retention'	chase Carnahan (b) (4)	01 Sep 2020 00:20:43

US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:20:43

**US3892033**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:20:43

**US3892033**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:20:43



US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:20:43

US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:20:43

US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2014'	System	01 Sep 2020 00:20:43

US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2014'	System	01 Sep 2020 00:20:43

**US3892033**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:20:43

US3892033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:20:43

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:21:41
Data point term sent to Coder	System	01 Sep 2020 00:21:14
User entered 'chronic low back pain'	chase Carnahan (b) (4)	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2018'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:07



US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2018'	System	01 Sep 2020 00:21:07

**US3892033**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2018'	System	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:21:07

US3892033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:21:07



US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 02:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 02:49:41
Data point term sent to Coder	System	01 Sep 2020 00:22:15
User entered 'chronic right shoulder pain'	chase Carnahan (b) (4)	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2018'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:22

**US3892033**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:20:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2018'	System	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2018'	System	01 Sep 2020 00:21:22



US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:21:22

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Clavicle fracture, LLT: Clavicle fracture - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:18:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:18:53
Data point term sent to Coder	System	20 Oct 2020 18:00:50
User closed query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Clavicle dislocation or ligament sprain or Subclavicular lymphadenopathy or something else.' (Site from System).	System	20 Oct 2020 17:59:56
Query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Clavicle dislocation or ligament sprain or Subclavicular lymphadenopathy or something else.' answered with 'Subject sustained fracture in 2018 which is still displaced' (Site from System).	Andryelle Toledo (b) (4)	20 Oct 2020 17:59:56
User entered 'displaced CLAVICAL (RIGHT)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	20 Oct 2020 17:59:53
Data point term sent to Coder	System	20 Oct 2020 17:57:45
Coding entries removed.	Andryelle Toledo (b) (4)	20 Oct 2020 17:56:53
User entered 'CLAVICAL Fracture (RIGHT)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	20 Oct 2020 17:56:53
User opened query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Clavicle dislocation or ligament sprain or Subclavicular lymphadenopathy or something else.' (Site from System).	Coder Import (b) (4)	08 Oct 2020 09:06:17

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Deformity, LLT: Deformity - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 05:36:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 05:36:45
Data point term sent to Coder	System	01 Sep 2020 00:22:14
User entered 'clavical deformity (right)'	chase Carnahan (b) (4)	01 Sep 2020 00:21:47
	(b) (4)	

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2018'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:47

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:47

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 17:59:53
User entered 'Yes (Y)'	chase Carnahan (b) (4)	01 Sep 2020 00:21:47
	(b) (4)	

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	20 Oct 2020 17:59:53
User entered empty.	(b) (4)	
	chase Carnahan (b) (4)	01 Sep 2020 00:21:47
	(b) (4)	



US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:21:47

US3892033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2018'	System	01 Sep 2020 00:21:47

**US3892033**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2018'	System	01 Sep 2020 00:21:47

**US3892033**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2018'	System	20 Oct 2020 17:59:53
User entered empty.	System	01 Sep 2020 00:21:47

**US3892033**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2018'	System	20 Oct 2020 17:59:53
User entered empty.	System	01 Sep 2020 00:21:47

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 06:14:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 06:14:49
Data point term sent to Coder	System	01 Sep 2020 00:23:15
User entered 'hearing loss (bilateral)'	chase Carnahan (b) (4)	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 1990'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:22:35



**US3892033**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 1990'	System	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1990'	System	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:22:35

US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 00:46:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 00:46:30
Data point term sent to Coder	System	29 Dec 2020 00:45:20
Coding entries removed.	Andryelle Toledo (b) (4)	29 Dec 2020 00:45:15
User entered 'Intermittent atrial fibrillation' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	29 Dec 2020 00:45:15
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:24:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 00:24:44
Data point term sent to Coder	System	01 Sep 2020 00:23:17
User entered 'arrhythmia'	chase Carnahan (b) (4)	01 Sep 2020 00:22:51



US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:22:51

US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:22:51

**US3892033**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:22:51

US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:22:51

US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:22:51

US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2014'	System	01 Sep 2020 00:22:51

US3892033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:20:41

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2014'	System	01 Sep 2020 00:22:51

**US3892033**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:22:51



**US3892033**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:22:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 18:48:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 18:48:30
Data point term sent to Coder	System	02 Feb 2021 18:47:55
User entered 'CORONARY ARTERY DISEASE'	Andryelle Toledo (b) (4)	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2014'	Andryelle Toledo (b) (4)	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Andryelle Toledo (b) (4)	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4)	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Andryelle Toledo (b) (4)	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2014'	System	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51



US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2014'	System	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:47:04
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	02 Feb 2021 18:46:43
DataPoint inactivated with code reason code Data not chase Carnahan required.	(b) (4)	01 Sep 2020 00:24:51

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug dependence, LLT: Opioid type dependence - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:25:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:25:59
Data point term sent to Coder	System	02 Feb 2021 18:48:56
Coding entries removed.	Andryelle Toledo (b) (4)	02 Feb 2021 18:48:08
User entered 'History Opioid Dependence' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Feb 2021 18:48:08
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 15:42:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 15:42:03
Data point term sent to Coder	System	27 Jan 2021 15:41:07
User entered 'Coronary Artery Disease'	Leslie Iverson (b) (4)	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	02 Feb 2021 18:48:26
User entered 'UN UNK 2004' reason for change: Data Entry Error	System	02 Feb 2021 18:48:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Andryelle Toledo (b) (4)	02 Feb 2021 18:48:26
User entered 'UN UNK 200' (non-conformant).	(b) (4)	02 Feb 2021 18:48:08
User entered 'UN UNK 2014' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	27 Jan 2021 15:45:48
User entered 'UN UNK 2005'	Leslie Iverson (b) (4)	27 Jan 2021 15:40:21

**US3892033**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 18:48:26
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'un UNK 2004' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	02 Feb 2021 18:48:26
User entered empty.	(b) (4)	
	Leslie Iverson (b) (4)	27 Jan 2021 15:40:21
	(b) (4)	



**US3892033**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 10:20:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2004'	System	02 Feb 2021 18:48:26
User entered empty.	System	02 Feb 2021 18:48:08
User entered 'Jan 2014'	System	27 Jan 2021 15:45:48
User entered 'Jan 2005'	System	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2004'	System	02 Feb 2021 18:48:26
User entered empty.	System	02 Feb 2021 18:48:08
User entered '2014'	System	27 Jan 2021 15:45:48
User entered '2005'	System	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'Jan 2004'	System	02 Feb 2021 18:48:26
User entered empty.	System	27 Jan 2021 15:40:21

**US3892033**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2004'	System	02 Feb 2021 18:48:26
User entered empty.	System	27 Jan 2021 15:40:21

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:45

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:45

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '12:30'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:45



US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '31 Aug 2020 12:30'	System	01 Sep 2020 00:17:45

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '182' cm	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45
DataPoint set to visible.	(b) (4) System	31 Aug 2020 19:18:59

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '97.2' kg	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45
DataPoint set to visible.	(b) (4) System	31 Aug 2020 19:18:59

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '29.34428'	System	01 Sep 2020 00:17:45
DataPoint set to visible.	System	31 Aug 2020 19:18:59

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'kg/m2'	System	01 Sep 2020 00:17:45
DataPoint set to visible.	System	31 Aug 2020 19:18:59

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:45

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:45



US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45

**US3892033**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:20:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'bpm'	System	01 Sep 2020 00:17:45

US3892033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'breaths/min'	System	01 Sep 2020 00:17:45

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	01 Sep 2020 00:17:45

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Folder: Screening

Form: Vital Signs

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Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:45

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	01 Sep 2020 00:17:45



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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:57

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:17:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

**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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 22:11:44
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Sep 2020 22:11:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Sep 2020 00:19:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Sep 2020 00:18:46
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

[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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

**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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

**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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

**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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 00:19:06
User entered 'No (N)' reason for change: Data Entry Error	chase Carnahan (b) (4)	01 Sep 2020 00:19:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Sep 2020 00:18:46
	chase Carnahan (b) (4)	01 Sep 2020 00:18:46
	(b) (4)	



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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:18:46

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'I'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46

US3892033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'I'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:18:46



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'drug store, book store, grocery store, library (has limited hours)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:18:46

US3892033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:19:24

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:19:24

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:19:24

**US3892033**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:20:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'VISIT1'	System	31 Aug 2020 19:19:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:19:48

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '189144'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:19:48

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:19:48



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:20:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:20:19

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:20:19

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:20:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:20:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:41

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 23:44:18
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:46:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:46:03

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35



US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Pre-Dose (PREDOSE)'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '12:30'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '31 Aug 2020 12:30'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '97.7' F	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35



US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Oral (Oral)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '68'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'bpm'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '15'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'breaths/min'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '123'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	01 Sep 2020 00:15:35



US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:50:35
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI: NCS' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 18:19:37
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:23:07
User entered '54'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered missing code ND - Not Done.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Post-Dose (POSTDOSE)'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '14:49'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35



US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '31 Aug 2020 14:49'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '97.7' F	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Oral (Oral)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '65'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'bpm'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '16'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'breaths/min'	System	01 Sep 2020 00:15:35



US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '128'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:51:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI: NCS' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 18:19:51
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:23:07
User entered '57'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	01 Sep 2020 00:15:35

US3892033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:16:09

US3892033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:16:09

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:36:00



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Folder: Visit 1 Day 1

Form: Exposure

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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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '13:59'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '31 Aug 2020 13:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'ONCE'	System	31 Aug 2020 20:36:00

US3892033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 20:36:00



US3892033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:37:25

US3892033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:37:25

US3892033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '13:35'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:37:25

US3892033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '31 Aug 2020 13:35'	System	31 Aug 2020 20:37:25

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:20:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '31 Aug 2020'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '13:30'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:16:58



US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '31 Aug 2020 13:30'	System	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:16:58

US3892033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:17:03

**US3892033**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	01 Sep 2020 00:17:03

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:44:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '934123eb-e5e0-43e6-b84e-78dd19857c0a' User entered 'Yes (Y)'	System	31 Aug 2020 20:48:34
	System	31 Aug 2020 20:48:34

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:44:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '934123eb-e5e0-43e6-b84e-78dd19857c0a' User entered '97.7'	System	31 Aug 2020 20:48:34
	System	31 Aug 2020 20:48:34

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:44:57', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '934123eb-e5e0-43e6-b84e-78dd19857c0a' User entered 'No (N)'	System	31 Aug 2020 20:48:34
	System	31 Aug 2020 20:48:34

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:45:09', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '934123eb-e5e0-43e6-b84e-78dd19857c0a' User entered '31 Aug 2020 14:45'	System	31 Aug 2020 20:48:34
	System	31 Aug 2020 20:48:34

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 14:19'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 16:49'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:51:41', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '98a8cc04-0766-4524-b74e-10ebe3b1d174' User entered 'Yes (Y)'	System	01 Sep 2020 01:52:14
	System	01 Sep 2020 01:52:14



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:51:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '98a8cc04-0766-4524-b74e-10ebe3b1d174' User entered '96.4'	System	01 Sep 2020 01:52:14
	System	01 Sep 2020 01:52:14

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:01', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '98a8cc04-0766-4524-b74e-10ebe3b1d174' User entered 'No (N)'	System	01 Sep 2020 01:52:14
	System	01 Sep 2020 01:52:14

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:10', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '98a8cc04-0766-4524-b74e-10ebe3b1d174' User entered '31 Aug 2020 19:52'	System	01 Sep 2020 01:52:14
	System	01 Sep 2020 01:52:14

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 17:44'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 2'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:22:17', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'bc58b491-6c16-45ef-87bf-3ffc4ed242af' User entered 'Yes (Y)'	System	01 Sep 2020 18:23:11
	System	01 Sep 2020 18:23:11

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:22:28', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'bc58b491-6c16-45ef-87bf-3ffc4ed242af' User entered '96.9'	System	01 Sep 2020 18:23:11
	System	01 Sep 2020 18:23:11



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:22:36', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'bc58b491-6c16-45ef-87bf-3ffc4ed242af' User entered 'Yes (Y)'	System	01 Sep 2020 18:23:11
	System	01 Sep 2020 18:23:11

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed subject took 500 mg of tylenol to treat headache. previous condition listed in medical history. ' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:44:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:25:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:22:45', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'bc58b491-6c16-45ef-87bf-3ffc4ed242af'	System	01 Sep 2020 18:23:11
User entered '1'	System	01 Sep 2020 18:23:11

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:22:45', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'bc58b491-6c16-45ef-87bf-3ffc4ed242af' User entered '0'	System	01 Sep 2020 18:23:11
	System	01 Sep 2020 18:23:11

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'bc58b491-6c16-45ef-87bf-3ffc4ed242af' User entered '01 Sep 2020 12:23'	System	01 Sep 2020 18:23:11
	System	01 Sep 2020 18:23:11

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 3'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:05:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e071d64f-f2a3-42a6-97c2-33159c277cba' User entered 'Yes (Y)'	System	02 Sep 2020 18:06:10
	System	02 Sep 2020 18:06:10



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:05:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e071d64f-f2a3-42a6-97c2-33159c277cba' User entered '97.5'	System	02 Sep 2020 18:06:10
	System	02 Sep 2020 18:06:10

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:05:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e071d64f-f2a3-42a6-97c2-33159c277cba' User entered 'Yes (Y)'	System	02 Sep 2020 18:06:10
	System	02 Sep 2020 18:06:10

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed subject took 500 mg of tylenol to treat headache. previous condition listed in medical history. ' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:44:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:25:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:05:38', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e071d64f-f2a3-42a6-97c2-33159c277cba'	System	02 Sep 2020 18:06:10
User entered '1'	System	02 Sep 2020 18:06:10

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:05:38', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e071d64f-f2a3-42a6-97c2-33159c277cba' User entered '0'	System	02 Sep 2020 18:06:10
	System	02 Sep 2020 18:06:10

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:08', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e071d64f-f2a3-42a6-97c2-33159c277cba' User entered '02 Sep 2020 12:06'	System	02 Sep 2020 18:06:10
	System	02 Sep 2020 18:06:10

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 4'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:29:51', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '2f93e055-63a2-41c3-a9ba-5ac831342d99'	System	03 Sep 2020 20:32:01
User entered 'Yes (Y)'	System	03 Sep 2020 20:32:01

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:31:21', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '2f93e055-63a2-41c3-a9ba-5ac831342d99' User entered '96.2'	System	03 Sep 2020 20:32:01
	System	03 Sep 2020 20:32:01

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:31:35', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '2f93e055-63a2-41c3-a9ba-5ac831342d99'	System	03 Sep 2020 20:32:01
User entered 'Yes (Y)'	System	03 Sep 2020 20:32:01

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed subject took 500 mg of tylenol to treat headache. previous condition listed in medical history. ' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:44:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:25:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:31:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '2f93e055-63a2-41c3-a9ba-5ac831342d99'	System	03 Sep 2020 20:32:01
User entered '1'	System	03 Sep 2020 20:32:01

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:31:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '2f93e055-63a2-41c3-a9ba-5ac831342d99'	System	03 Sep 2020 20:32:01
User entered '0'	System	03 Sep 2020 20:32:01

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:31:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '2f93e055-63a2-41c3-a9ba-5ac831342d99'	System	03 Sep 2020 20:32:01
User entered '03 Sep 2020 14:31'	System	03 Sep 2020 20:32:01

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 5'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4814b0d4-e249-47a3-83cb-694f7aed7d13' User entered 'Yes (Y)'	System	04 Sep 2020 18:54:46
	System	04 Sep 2020 18:54:46

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:21', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4814b0d4-e249-47a3-83cb-694f7aed7d13' User entered '97.8'	System	04 Sep 2020 18:54:46
	System	04 Sep 2020 18:54:46

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4814b0d4-e249-47a3-83cb-694f7aed7d13'	System	04 Sep 2020 18:54:46
User entered 'Yes (Y)'	System	04 Sep 2020 18:54:46

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed subject took 500 mg of tylenol to treat headache. previous condition listed in medical history. ' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:45:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:26:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4814b0d4-e249-47a3-83cb-694f7aed7d13'	System	04 Sep 2020 18:54:46
User entered '1'	System	04 Sep 2020 18:54:46

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4814b0d4-e249-47a3-83cb-694f7aed7d13' User entered '0'	System	04 Sep 2020 18:54:46
	System	04 Sep 2020 18:54:46

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4814b0d4-e249-47a3-83cb-694f7aed7d13' User entered '04 Sep 2020 12:54'	System	04 Sep 2020 18:54:46
	System	04 Sep 2020 18:54:46

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 6'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:41:57', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dba8608d-7af0-4eba-84f8-67859b58e487' User entered 'Yes (Y)'	System	06 Sep 2020 16:45:56
	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:43:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dba8608d-7af0-4eba-84f8-67859b58e487' User entered '97.2'	System	06 Sep 2020 16:45:56
	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:44:36', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dba8608d-7af0-4eba-84f8-67859b58e487'	System	06 Sep 2020 16:45:56
User entered 'Yes (Y)'	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed subject took 500 mg of tylenol to treat headache. previous condition listed in medical history. ' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:45:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:26:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:45:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dba8608d-7af0-4eba-84f8-67859b58e487'	System	06 Sep 2020 16:45:56
User entered '1'	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:45:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dba8608d-7af0-4eba-84f8-67859b58e487' User entered '0'	System	06 Sep 2020 16:45:56
	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:45:53', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dba8608d-7af0-4eba-84f8-67859b58e487' User entered '06 Sep 2020 10:45'	System	06 Sep 2020 16:45:56
	System	06 Sep 2020 16:45:56



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 7'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:18:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a92a83f8-7362-4585-849f-3fb6ecce1e25'	System	07 Sep 2020 12:19:33
User entered 'Yes (Y)'	System	07 Sep 2020 12:19:33

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:18:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a92a83f8-7362-4585-849f-3fb6ecce1e25' User entered '97.1'	System	07 Sep 2020 12:19:33
	System	07 Sep 2020 12:19:33

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:19:13', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a92a83f8-7362-4585-849f-3fb6ecce1e25'	System	07 Sep 2020 12:19:33
User entered 'No (N)'	System	07 Sep 2020 12:19:33

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:19:24', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a92a83f8-7362-4585-849f-3fb6ecce1e25' User entered '07 Sep 2020 06:19'	System	07 Sep 2020 12:19:33
	System	07 Sep 2020 12:19:33

US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:37', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3e865d6d-baef-4855-8ee1-1a983a9cfda9' User entered 'None (1)'	System	31 Aug 2020 20:48:58
	System	31 Aug 2020 20:48:58

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3e865d6d-baef-4855-8ee1-1a983a9cfda9' User entered 'No (N)'	System	31 Aug 2020 20:48:58
	System	31 Aug 2020 20:48:58

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3e865d6d-baef-4855-8ee1-1a983a9cfda9' User entered 'No (N)'	System	31 Aug 2020 20:48:58
	System	31 Aug 2020 20:48:58

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3e865d6d-baef-4855-8ee1-1a983a9cfda9' User entered 'None (1)'	System	31 Aug 2020 20:48:58
	System	31 Aug 2020 20:48:58

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:47:05', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3e865d6d-baef-4855-8ee1-1a983a9cfda9' User entered '31 Aug 2020 14:47'	System	31 Aug 2020 20:48:58
	System	31 Aug 2020 20:48:58

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 14:19'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 16:49'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:53:03', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '49bb2372-d543-4680-860a-52382634b2a3' User entered 'None (1)'	System	01 Sep 2020 01:53:25
	System	01 Sep 2020 01:53:25

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:53:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '49bb2372-d543-4680-860a-52382634b2a3' User entered 'No (N)'	System	01 Sep 2020 01:53:25
	System	01 Sep 2020 01:53:25

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:53:12', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '49bb2372-d543-4680-860a-52382634b2a3' User entered 'No (N)'	System	01 Sep 2020 01:53:25
	System	01 Sep 2020 01:53:25

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:53:16', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '49bb2372-d543-4680-860a-52382634b2a3' User entered 'None (1)'	System	01 Sep 2020 01:53:25
	System	01 Sep 2020 01:53:25

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:53:23', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '49bb2372-d543-4680-860a-52382634b2a3' User entered '31 Aug 2020 19:53'	System	01 Sep 2020 01:53:25
	System	01 Sep 2020 01:53:25

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 17:44'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 2'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '425335f5-f25f-4677-ab36-a0b35fb9bde4'	System	01 Sep 2020 18:24:49
User entered 'None (1)'	System	01 Sep 2020 18:24:49

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:26', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '425335f5-f25f-4677-ab36-a0b35fb9bde4' User entered 'No (N)'	System	01 Sep 2020 18:24:49
	System	01 Sep 2020 18:24:49

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '425335f5-f25f-4677-ab36-a0b35fb9bde4' User entered 'No (N)'	System	01 Sep 2020 18:24:49
	System	01 Sep 2020 18:24:49

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '425335f5-f25f-4677-ab36-a0b35fb9bde4'	System	01 Sep 2020 18:24:49
User entered 'None (1)'	System	01 Sep 2020 18:24:49

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '425335f5-f25f-4677-ab36-a0b35fb9bde4' User entered '01 Sep 2020 12:24'	System	01 Sep 2020 18:24:49
	System	01 Sep 2020 18:24:49

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 3'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:17', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8e862020-bd52-4be1-8253-d953921cc7b6'	System	02 Sep 2020 18:06:42
User entered 'None (1)'	System	02 Sep 2020 18:06:42

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:21', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8e862020-bd52-4be1-8253-d953921cc7b6'	System	02 Sep 2020 18:06:42
User entered 'No (N)'	System	02 Sep 2020 18:06:42

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:24', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8e862020-bd52-4be1-8253-d953921cc7b6'	System	02 Sep 2020 18:06:42
User entered 'No (N)'	System	02 Sep 2020 18:06:42

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:29', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8e862020-bd52-4be1-8253-d953921cc7b6'	System	02 Sep 2020 18:06:42
User entered 'None (1)'	System	02 Sep 2020 18:06:42

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8e862020-bd52-4be1-8253-d953921cc7b6' User entered '02 Sep 2020 12:06'	System	02 Sep 2020 18:06:42
	System	02 Sep 2020 18:06:42

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 4'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:32:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7bfbb295-53f6-4e29-a52e-f449e7253fb1' User entered 'None (1)'	System	03 Sep 2020 20:32:28
	System	03 Sep 2020 20:32:28

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:32:09', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7bfbb295-53f6-4e29-a52e-f449e7253fb1' User entered 'No (N)'	System	03 Sep 2020 20:32:28
	System	03 Sep 2020 20:32:28

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:32:12', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7bfbb295-53f6-4e29-a52e-f449e7253fb1' User entered 'No (N)'	System	03 Sep 2020 20:32:28
	System	03 Sep 2020 20:32:28

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:32:17', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7bfbb295-53f6-4e29-a52e-f449e7253fb1' User entered 'None (1)'	System	03 Sep 2020 20:32:28
	System	03 Sep 2020 20:32:28

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:32:24', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7bfbb295-53f6-4e29-a52e-f449e7253fb1' User entered '03 Sep 2020 14:32'	System	03 Sep 2020 20:32:28
	System	03 Sep 2020 20:32:28

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 5'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '245628d4-b081-4181-8f7c-8aa181b3cb0e' User entered 'None (1)'	System	04 Sep 2020 18:55:07
	System	04 Sep 2020 18:55:07

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '245628d4-b081-4181-8f7c-8aa181b3cb0e' User entered 'No (N)'	System	04 Sep 2020 18:55:07
	System	04 Sep 2020 18:55:07

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '245628d4-b081-4181-8f7c-8aa181b3cb0e' User entered 'No (N)'	System	04 Sep 2020 18:55:07
	System	04 Sep 2020 18:55:07

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:54:56', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '245628d4-b081-4181-8f7c-8aa181b3cb0e' User entered 'None (1)'	System	04 Sep 2020 18:55:07
	System	04 Sep 2020 18:55:07

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:55:03', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '245628d4-b081-4181-8f7c-8aa181b3cb0e' User entered '04 Sep 2020 12:55'	System	04 Sep 2020 18:55:07
	System	04 Sep 2020 18:55:07

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 6'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:46:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '03af52b3-67c4-4f8d-acb9-5fa57e1bd4c6' User entered 'None (1)'	System	06 Sep 2020 16:48:38
	System	06 Sep 2020 16:48:38

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:47:14', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '03af52b3-67c4-4f8d-acb9-5fa57e1bd4c6' User entered 'No (N)'	System	06 Sep 2020 16:48:38
	System	06 Sep 2020 16:48:38

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:47:41', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '03af52b3-67c4-4f8d-acb9-5fa57e1bd4c6' User entered 'No (N)'	System	06 Sep 2020 16:48:38
	System	06 Sep 2020 16:48:38

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:48:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '03af52b3-67c4-4f8d-acb9-5fa57e1bd4c6' User entered 'None (1)'	System	06 Sep 2020 16:48:38
	System	06 Sep 2020 16:48:38

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:48:35', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '03af52b3-67c4-4f8d-acb9-5fa57e1bd4c6' User entered '06 Sep 2020 10:48'	System	06 Sep 2020 16:48:38
	System	06 Sep 2020 16:48:38

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 7'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:19:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '56fc38a5-5c38-47e4-9f18-8807b525c61d' User entered 'None (1)'	System	07 Sep 2020 12:20:32
	System	07 Sep 2020 12:20:32

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:19:36', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '56fc38a5-5c38-47e4-9f18-8807b525c61d' User entered 'No (N)'	System	07 Sep 2020 12:20:32
	System	07 Sep 2020 12:20:32

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:19:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '56fc38a5-5c38-47e4-9f18-8807b525c61d' User entered 'No (N)'	System	07 Sep 2020 12:20:32
	System	07 Sep 2020 12:20:32

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:20:13', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '56fc38a5-5c38-47e4-9f18-8807b525c61d' User entered 'None (1)'	System	07 Sep 2020 12:20:32
	System	07 Sep 2020 12:20:32

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:20:28', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '56fc38a5-5c38-47e4-9f18-8807b525c61d' User entered '07 Sep 2020 06:20'	System	07 Sep 2020 12:20:32
	System	07 Sep 2020 12:20:32

US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:45:26', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'None (0)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:45:36', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'None (0)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:45:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'None (0)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:45:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'None (0)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:00', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'None (0)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:03', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'None (0)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:09', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered 'No (N)'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T14:46:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d1967c7-0439-49e0-b604-f67ab05c8b5d' User entered '31 Aug 2020 14:46'	System	31 Aug 2020 20:48:52
	System	31 Aug 2020 20:48:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 14:19'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 16:49'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:19', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'None (0)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:23', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'None (0)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:29', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'No interference with activity (1)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'No interference with activity (1)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'None (0)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'None (0)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered 'No (N)'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-08-31T19:52:56', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '5b89eb9b-53c0-401d-ad0e-a41760dead5c' User entered '31 Aug 2020 19:52'	System	01 Sep 2020 01:52:57
	System	01 Sep 2020 01:52:57

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '31 Aug 2020 17:44'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 2'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered 'No interference with activity (1)'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f'	System	01 Sep 2020 18:24:17
User entered 'Some interference with activity (2)'	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered 'No interference with activity (1)'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:42', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered 'No interference with activity (1)'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered 'None (0)'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:23:51', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered 'None (0)'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:01', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered 'No (N)'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-01T12:24:13', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '58037f1f-b09e-4f60-ae54-87d6fc6b164f' User entered '01 Sep 2020 12:24'	System	01 Sep 2020 18:24:17
	System	01 Sep 2020 18:24:17



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 3'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:06:50', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86'	System	02 Sep 2020 18:07:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:01', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86'	System	02 Sep 2020 18:07:41
User entered 'Some interference with activity (2)'	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86'	System	02 Sep 2020 18:07:41
User entered 'Some interference with activity (2)'	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:10', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86'	System	02 Sep 2020 18:07:41
User entered 'Some interference with activity (2)'	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:14', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86' User entered 'None (0)'	System	02 Sep 2020 18:07:41
	System	02 Sep 2020 18:07:41



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:19', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86'	System	02 Sep 2020 18:07:41
User entered 'No interference with activity (1)'	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86' User entered 'No (N)'	System	02 Sep 2020 18:07:41
	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-02T12:07:37', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e1194138-97ea-45c6-b03f-cc4c05e09b86' User entered '02 Sep 2020 12:07'	System	02 Sep 2020 18:07:41
	System	02 Sep 2020 18:07:41

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 4'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:09', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6'	System	03 Sep 2020 20:33:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:13', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6'	System	03 Sep 2020 20:33:52
User entered 'Some interference with activity (2)'	System	03 Sep 2020 20:33:52



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:23', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6'	System	03 Sep 2020 20:33:52
User entered 'Some interference with activity (2)'	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6'	System	03 Sep 2020 20:33:52
User entered 'Some interference with activity (2)'	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6' User entered 'None (0)'	System	03 Sep 2020 20:33:52
	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:37', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6' User entered 'None (0)'	System	03 Sep 2020 20:33:52
	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:41', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6' User entered 'No (N)'	System	03 Sep 2020 20:33:52
	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-03T14:33:50', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8d3ccabf-c523-4d21-ba6d-f6c79bc054f6' User entered '03 Sep 2020 14:33'	System	03 Sep 2020 20:33:52
	System	03 Sep 2020 20:33:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 5'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:52:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5'	System	04 Sep 2020 18:53:51
User entered 'No interference with activity (1)'	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5'	System	04 Sep 2020 18:53:51
User entered 'Some interference with activity (2)'	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:14', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5'	System	04 Sep 2020 18:53:51
User entered 'No interference with activity (1)'	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5'	System	04 Sep 2020 18:53:51
User entered 'No interference with activity (1)'	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5' User entered 'None (0)'	System	04 Sep 2020 18:53:51
	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:29', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5' User entered 'None (0)'	System	04 Sep 2020 18:53:51
	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:33', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5' User entered 'No (N)'	System	04 Sep 2020 18:53:51
	System	04 Sep 2020 18:53:51



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-04T12:53:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a20bcea9-836b-4868-a5f9-e18bf8dd31c5' User entered '04 Sep 2020 12:53'	System	04 Sep 2020 18:53:51
	System	04 Sep 2020 18:53:51

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 6'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:48:50', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9'	System	06 Sep 2020 16:53:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:49:30', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9'	System	06 Sep 2020 16:53:55
User entered 'Some interference with activity (2)'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:51:02', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9'	System	06 Sep 2020 16:53:55
User entered 'No interference with activity (1)'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:51:24', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9'	System	06 Sep 2020 16:53:55
User entered 'No interference with activity (1)'	System	06 Sep 2020 16:53:55



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:52:42', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9' User entered 'None (0)'	System	06 Sep 2020 16:53:55
	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:52:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9' User entered 'None (0)'	System	06 Sep 2020 16:53:55
	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:53:33', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9' User entered 'No (N)'	System	06 Sep 2020 16:53:55
	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-06T10:53:54', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a938c503-444a-4f62-be94-c86761275cd9' User entered '06 Sep 2020 10:53'	System	06 Sep 2020 16:53:55
	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 7'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:20:44', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980'	System	07 Sep 2020 12:23:52
User entered 'No interference with activity (1)'	System	07 Sep 2020 12:23:52



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:22:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980'	System	07 Sep 2020 12:23:52
User entered 'Significant; prevents daily activity (3)'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:21:36', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980' User entered 'None (0)'	System	07 Sep 2020 12:23:52
	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:21:44', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980' User entered 'None (0)'	System	07 Sep 2020 12:23:52
	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:22:10', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980' User entered 'None (0)'	System	07 Sep 2020 12:23:52
	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:22:16', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980' User entered 'None (0)'	System	07 Sep 2020 12:23:52
	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:22:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980' User entered 'No (N)'	System	07 Sep 2020 12:23:52
	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T06:23:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '800b08f9-01d8-4cf4-ac3c-87d19775d980' User entered '07 Sep 2020 06:23'	System	07 Sep 2020 12:23:52
	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:36:00



US3892033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	06 Sep 2020 16:53:55
User entered 'Day 8'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T12:17:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '59c8d8f4-d8bf-4f53-b117-a26ae0d9cf4e'	System	07 Sep 2020 18:18:08
User entered 'No interference with activity (1)'	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T12:18:05', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '59c8d8f4-d8bf-4f53-b117-a26ae0d9cf4e' User entered '07 Sep 2020 12:18'	System	07 Sep 2020 18:18:08
	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	07 Sep 2020 12:23:52
User entered 'Day 9'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-08T13:03:44', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0ebfef71-7a26-47fa-b24c-6df605b716f7'	System	08 Sep 2020 19:04:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Sep 2020 19:04:08



US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-08T13:04:04', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0ebfef71-7a26-47fa-b24c-6df605b716f7' User entered '08 Sep 2020 13:04'	System	08 Sep 2020 19:04:08
	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	07 Sep 2020 18:18:08
User entered 'Day 10'	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 18:18:08



US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	08 Sep 2020 19:04:08
User entered 'Day 11'	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-10T19:46:53', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '91a7b790-d3b1-4d86-a00e-23f97597bb2e' User entered 'None (0)'	System	11 Sep 2020 01:47:14
	System	11 Sep 2020 01:47:14

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-10T19:47:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '91a7b790-d3b1-4d86-a00e-23f97597bb2e' User entered '10 Sep 2020 19:47'	System	11 Sep 2020 01:47:14
	System	11 Sep 2020 01:47:14

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	06 Sep 2020 16:53:55
User entered 'Day 8'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T12:18:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '6fb98a89-17fe-450c-ba34-cdf122f1a0ef'	System	07 Sep 2020 18:19:25
User entered 'No interference with activity (1)'	System	07 Sep 2020 18:19:25

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T12:19:21', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '6fb98a89-17fe-450c-ba34-cdf122f1a0ef' User entered '07 Sep 2020 12:19'	System	07 Sep 2020 18:19:25
	System	07 Sep 2020 18:19:25



US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 16:53:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	07 Sep 2020 12:23:52
User entered 'Day 9'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-08T13:04:42', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3ca12b55-2ae9-4b60-9b04-bbec67e69766'	System	08 Sep 2020 19:04:55
User entered 'Some interference with activity (2)'	System	08 Sep 2020 19:04:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-08T13:04:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '3ca12b55-2ae9-4b60-9b04-bbec67e69766' User entered '08 Sep 2020 13:04'	System	08 Sep 2020 19:04:55
	System	08 Sep 2020 19:04:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	07 Sep 2020 18:19:25
User entered 'Day 10'	System	07 Sep 2020 18:19:25



US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 18:19:25

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 18:19:25

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	08 Sep 2020 19:04:55
User entered 'Day 11'	System	08 Sep 2020 19:04:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-10T19:47:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ac4a3002-c875-4e0a-9104-ed7519361f76'	System	11 Sep 2020 01:47:49
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-10T19:47:46', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ac4a3002-c875-4e0a-9104-ed7519361f76' User entered '10 Sep 2020 19:47'	System	11 Sep 2020 01:47:49
	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:04:55



US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:04:55

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	11 Sep 2020 01:47:49
User entered 'Day 12'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	11 Sep 2020 01:47:49
User entered 'Day 13'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 10 Jun 2021 10:20:41

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52



US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	06 Sep 2020 16:45:56
User entered 'Day 8'	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T12:20:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '9a659ed3-d433-45ca-844d-5ed4456d11ea' User entered 'Yes (Y)'	System	07 Sep 2020 18:20:39
	System	07 Sep 2020 18:20:39

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-07T12:20:37', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '9a659ed3-d433-45ca-844d-5ed4456d11ea' User entered '07 Sep 2020 12:20'	System	07 Sep 2020 18:20:39
	System	07 Sep 2020 18:20:39

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 16:45:56

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 16:45:56



US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	07 Sep 2020 12:23:52
User entered 'Day 9'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-08T13:05:14', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '89271433-deb0-4876-a73c-acd9a7adeafb' User entered 'Yes (Y)'	System	08 Sep 2020 19:05:27
	System	08 Sep 2020 19:05:27

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-08T13:05:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '89271433-deb0-4876-a73c-acd9a7adeafb' User entered '08 Sep 2020 13:05'	System	08 Sep 2020 19:05:27
	System	08 Sep 2020 19:05:27

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 12:23:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	07 Sep 2020 18:18:08
User entered 'Day 10'	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52



US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 18:18:08

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	08 Sep 2020 19:04:08
User entered 'Day 11'	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-10T19:48:10', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '00a5e3dd-b6b9-4f2b-bb87-6bff8250c57c' User entered 'No (N)'	System	11 Sep 2020 01:48:27
	System	11 Sep 2020 01:48:27

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-10T19:48:23', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '00a5e3dd-b6b9-4f2b-bb87-6bff8250c57c' User entered '10 Sep 2020 19:48'	System	11 Sep 2020 01:48:27
	System	11 Sep 2020 01:48:27

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:04:08

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	11 Sep 2020 01:47:49
User entered 'Day 12'	System	11 Sep 2020 01:47:49



US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	11 Sep 2020 01:47:49
User entered 'Day 13'	System	11 Sep 2020 01:47:49

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52

US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 01:47:49



US3892033

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 01:47:49

US3892033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	09 Sep 2020 21:09:12

US3892033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Sep 2020 23:08:49
User entered '8 Sep 2020'	Stefanie Vasconez (b) (4)	09 Sep 2020 21:09:12
	(b) (4)	

US3892033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	11 Sep 2020 23:08:49
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Stefanie Vasconez (b) (4)	09 Sep 2020 21:09:12
	(b) (4)	

US3892033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'CRC CALLED, EMAILED AND TEXTED SUBJECT REGARDING SAFETY CALL. SUBJECT IS UNREACHABLE. PI was able to get a hold of subject.' reason for change: Data Entry Error	Stefanie Vasconez (b) (4)	11 Sep 2020 23:08:49
User entered 'CRC called, emailed and texted subject regarding safety call. Subject is unreachable'	Stefanie Vasconez (b) (4)	09 Sep 2020 21:09:12

US3892033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	09 Sep 2020 21:09:28

**US3892033**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	09 Sep 2020 21:09:28

US3892033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	15 Sep 2020 01:24:37



US3892033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '14 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	15 Sep 2020 01:24:37

US3892033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	15 Sep 2020 01:24:37

US3892033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Stefanie Vasconez (b) (4)	15 Sep 2020 01:24:37

US3892033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	15 Sep 2020 01:25:24

US3892033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	15 Sep 2020 01:25:24

US3892033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:31:37

US3892033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '21 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:31:37

US3892033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:31:37



US3892033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:31:37

US3892033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:32:52

US3892033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	21 Sep 2020 23:32:52

US3892033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:38:58

US3892033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:38:58

US3892033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Clinic (Clinic)'	(b) (4) chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:38:58

US3892033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'VISIT2'	System	28 Sep 2020 17:38:58

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57
	(b) (4)	



US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '10:42'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '28 Sep 2020 10:42'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '98.4' F	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '65'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57



US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'bpm'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '14'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'breaths/min'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '129'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:22:31
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI: NCS' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:17:44
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Sep 2020 19:14:57
User entered '54'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:14:57



US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '12:02'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '28 Sep 2020 12:02'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '98.2' F	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '60'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57



US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'bpm'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '14'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'breaths/min'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '134'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:22:38
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI: NCS' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:17:55
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Sep 2020 19:14:57
User entered '58'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	28 Sep 2020 19:14:57

US3892033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:39:11



US3892033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:39:11

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '11:30'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '28 Sep 2020 11:30'	System	28 Sep 2020 17:39:35



US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'ONCE'	System	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 17:39:35

US3892033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:40:04

US3892033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:40:04

US3892033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '11:29'	(b) (4) chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:40:04

US3892033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '28 Sep 2020 11:29'	System	28 Sep 2020 17:40:04

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:20:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '28 Sep 2020'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:40:24



US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	chase Carnahan (b) (4)	28 Sep 2020 17:40:24

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	13 Oct 2020 18:20:01
	(b) (4)	
User entered 'No (N)'	chase Carnahan (b) (4)	28 Sep 2020 17:40:24
	(b) (4)	

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '11:05' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 18:20:01
User entered empty.	chase Carnahan (b) (4)	28 Sep 2020 17:40:24
	(b) (4)	

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '28 Sep 2020 11:05'	System	13 Oct 2020 18:20:01
User entered empty.	System	28 Sep 2020 17:40:24

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	chase Carnahan (b) (4) (b) (4)	28 Sep 2020 17:40:24

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 18:20:01
User entered 'Yes (Y)'	chase Carnahan (b) (4)	28 Sep 2020 17:40:24
	(b) (4)	

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:20:01
User entered '11:05'	Andryelle Toledo (b) (4)	13 Oct 2020 18:20:01
	(b) (4)	
	chase Carnahan (b) (4)	28 Sep 2020 17:40:24
	(b) (4)	

US3892033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	13 Oct 2020 18:20:01
User entered '28 Sep 2020 11:05'	System	28 Sep 2020 17:40:24



US3892033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	28 Sep 2020 17:40:28

US3892033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	28 Sep 2020 17:40:28

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:04:32', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4fd217dc-0b09-41fb-8a3c-d40d2c39c68f' User entered 'Yes (Y)'	System	28 Sep 2020 18:04:59
	System	28 Sep 2020 18:04:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:04:42', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4fd217dc-0b09-41fb-8a3c-d40d2c39c68f' User entered '98.2'	System	28 Sep 2020 18:04:59
	System	28 Sep 2020 18:04:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:04:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4fd217dc-0b09-41fb-8a3c-d40d2c39c68f' User entered 'No (N)'	System	28 Sep 2020 18:04:59
	System	28 Sep 2020 18:04:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:04:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '4fd217dc-0b09-41fb-8a3c-d40d2c39c68f' User entered '28 Sep 2020 12:04'	System	28 Sep 2020 18:04:59
	System	28 Sep 2020 18:04:59

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 17:39:35



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ede9ae9f-7e3b-4865-b044-5dc1ca99921a' User entered 'Yes (Y)'	System	29 Sep 2020 14:47:46
	System	29 Sep 2020 14:47:46

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ede9ae9f-7e3b-4865-b044-5dc1ca99921a' User entered '97.5'	System	29 Sep 2020 14:47:46
	System	29 Sep 2020 14:47:46

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ede9ae9f-7e3b-4865-b044-5dc1ca99921a' User entered 'No (N)'	System	29 Sep 2020 14:47:46
	System	29 Sep 2020 14:47:46

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ede9ae9f-7e3b-4865-b044-5dc1ca99921a' User entered '29 Sep 2020 08:47'	System	29 Sep 2020 14:47:46
	System	29 Sep 2020 14:47:46

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 17:39:35



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 2'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:04:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a6ed8c9e-4109-49a5-8be8-a0a5384ab102'	System	29 Sep 2020 18:04:55
User entered 'Yes (Y)'	System	29 Sep 2020 18:04:55

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:04:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a6ed8c9e-4109-49a5-8be8-a0a5384ab102' User entered '95.6'	System	29 Sep 2020 18:04:55
	System	29 Sep 2020 18:04:55

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:04:45', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a6ed8c9e-4109-49a5-8be8-a0a5384ab102'	System	29 Sep 2020 18:04:55
User entered 'No (N)'	System	29 Sep 2020 18:04:55

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:04:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a6ed8c9e-4109-49a5-8be8-a0a5384ab102' User entered '29 Sep 2020 12:04'	System	29 Sep 2020 18:04:55
	System	29 Sep 2020 18:04:55

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 3'	System	28 Sep 2020 17:39:35



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:03:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ba39b7cd-7ae7-481b-82fb-d6f1e616d863' User entered 'Yes (Y)'	System	30 Sep 2020 18:04:10
	System	30 Sep 2020 18:04:10

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:03:56', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ba39b7cd-7ae7-481b-82fb-d6f1e616d863' User entered '97.5'	System	30 Sep 2020 18:04:10
	System	30 Sep 2020 18:04:10

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:00', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ba39b7cd-7ae7-481b-82fb-d6f1e616d863' User entered 'No (N)'	System	30 Sep 2020 18:04:10
	System	30 Sep 2020 18:04:10

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ba39b7cd-7ae7-481b-82fb-d6f1e616d863' User entered '30 Sep 2020 12:04'	System	30 Sep 2020 18:04:10
	System	30 Sep 2020 18:04:10

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 4'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:19', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '609c4952-36d5-4ccf-a359-4da49310a150' User entered 'Yes (Y)'	System	01 Oct 2020 18:59:44
	System	01 Oct 2020 18:59:44



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:30', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '609c4952-36d5-4ccf-a359-4da49310a150' User entered '95.6'	System	01 Oct 2020 18:59:44
	System	01 Oct 2020 18:59:44

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:35', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '609c4952-36d5-4ccf-a359-4da49310a150'	System	01 Oct 2020 18:59:44
User entered 'No (N)'	System	01 Oct 2020 18:59:44

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '609c4952-36d5-4ccf-a359-4da49310a150' User entered '01 Oct 2020 12:59'	System	01 Oct 2020 18:59:44
	System	01 Oct 2020 18:59:44

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 5'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:33:45', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e821e9e7-0466-4285-9d32-a783ab6d142e' User entered 'Yes (Y)'	System	02 Oct 2020 19:34:06
	System	02 Oct 2020 19:34:06

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:33:53', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e821e9e7-0466-4285-9d32-a783ab6d142e' User entered '95.7'	System	02 Oct 2020 19:34:06
	System	02 Oct 2020 19:34:06



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:33:58', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e821e9e7-0466-4285-9d32-a783ab6d142e' User entered 'No (N)'	System	02 Oct 2020 19:34:06
	System	02 Oct 2020 19:34:06

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:04', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'e821e9e7-0466-4285-9d32-a783ab6d142e' User entered '02 Oct 2020 13:34'	System	02 Oct 2020 19:34:06
	System	02 Oct 2020 19:34:06

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 6'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:01', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7408ac75-7200-4454-88fd-b9c6a2090bba' User entered 'Yes (Y)'	System	03 Oct 2020 18:36:26
	System	03 Oct 2020 18:36:26

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:09', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7408ac75-7200-4454-88fd-b9c6a2090bba' User entered '95.7'	System	03 Oct 2020 18:36:26
	System	03 Oct 2020 18:36:26

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:20', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7408ac75-7200-4454-88fd-b9c6a2090bba' User entered 'No (N)'	System	03 Oct 2020 18:36:26
	System	03 Oct 2020 18:36:26



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:23', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7408ac75-7200-4454-88fd-b9c6a2090bba' User entered '03 Oct 2020 12:36'	System	03 Oct 2020 18:36:26
	System	03 Oct 2020 18:36:26

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 7'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:48:54', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7d2e6e40-8bc3-471e-be5a-2cbf05ec1cfa' User entered 'Yes (Y)'	System	04 Oct 2020 18:49:16
	System	04 Oct 2020 18:49:16

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:02', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7d2e6e40-8bc3-471e-be5a-2cbf05ec1cfa' User entered '95.6'	System	04 Oct 2020 18:49:16
	System	04 Oct 2020 18:49:16

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7d2e6e40-8bc3-471e-be5a-2cbf05ec1cfa' User entered 'No (N)'	System	04 Oct 2020 18:49:16
	System	04 Oct 2020 18:49:16

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '7d2e6e40-8bc3-471e-be5a-2cbf05ec1cfa' User entered '04 Oct 2020 12:49'	System	04 Oct 2020 18:49:16
	System	04 Oct 2020 18:49:16



US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'fd59f439-4087-4aff-9dba-42cad591433'	System	28 Sep 2020 18:05:28
User entered 'None (1)'	System	28 Sep 2020 18:05:28

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'fd59f439-4087-4aff-9dba-42cad591433'	System	28 Sep 2020 18:05:28
User entered 'No (N)'	System	28 Sep 2020 18:05:28

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:16', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'fd59f439-4087-4aff-9dba-42cad591433'	System	28 Sep 2020 18:05:28
User entered 'No (N)'	System	28 Sep 2020 18:05:28

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:19', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'fd59f439-4087-4aff-9dba-42cad591433'	System	28 Sep 2020 18:05:28
User entered 'None (1)'	System	28 Sep 2020 18:05:28

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'fd59f439-4087-4aff-9dba-42cad591433'	System	28 Sep 2020 18:05:28
User entered '28 Sep 2020 12:05'	System	28 Sep 2020 18:05:28



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a5d472af-61ef-45fa-a150-e8e9b715a12a'	System	29 Sep 2020 14:48:01
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 14:48:01

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a5d472af-61ef-45fa-a150-e8e9b715a12a' User entered 'No (N)'	System	29 Sep 2020 14:48:01
	System	29 Sep 2020 14:48:01

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:48', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a5d472af-61ef-45fa-a150-e8e9b715a12a' User entered 'No (N)'	System	29 Sep 2020 14:48:01
	System	29 Sep 2020 14:48:01

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:54', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a5d472af-61ef-45fa-a150-e8e9b715a12a'	System	29 Sep 2020 14:48:01
User entered 'None (1)'	System	29 Sep 2020 14:48:01

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:47:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a5d472af-61ef-45fa-a150-e8e9b715a12a' User entered '29 Sep 2020 08:47'	System	29 Sep 2020 14:48:01
	System	29 Sep 2020 14:48:01



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 2'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:04:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dc57af07-8b84-4984-87d4-f2eb0de34397'	System	29 Sep 2020 18:05:25
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 18:05:25

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:02', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dc57af07-8b84-4984-87d4-f2eb0de34397' User entered 'No (N)'	System	29 Sep 2020 18:05:25
	System	29 Sep 2020 18:05:25

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:12', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dc57af07-8b84-4984-87d4-f2eb0de34397' User entered 'No (N)'	System	29 Sep 2020 18:05:25
	System	29 Sep 2020 18:05:25

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dc57af07-8b84-4984-87d4-f2eb0de34397'	System	29 Sep 2020 18:05:25
User entered 'None (1)'	System	29 Sep 2020 18:05:25

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'dc57af07-8b84-4984-87d4-f2eb0de34397' User entered '29 Sep 2020 12:05'	System	29 Sep 2020 18:05:25
	System	29 Sep 2020 18:05:25



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 3'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ed176b5c-c58d-4069-b2d6-7cce6a98cd7a' User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 18:04:37
	System	30 Sep 2020 18:04:37

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:21', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ed176b5c-c58d-4069-b2d6-7cce6a98cd7a' User entered 'No (N)'	System	30 Sep 2020 18:04:37
	System	30 Sep 2020 18:04:37

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ed176b5c-c58d-4069-b2d6-7cce6a98cd7a' User entered 'No (N)'	System	30 Sep 2020 18:04:37
	System	30 Sep 2020 18:04:37

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:30', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ed176b5c-c58d-4069-b2d6-7cce6a98cd7a' User entered 'None (1)'	System	30 Sep 2020 18:04:37
	System	30 Sep 2020 18:04:37

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ed176b5c-c58d-4069-b2d6-7cce6a98cd7a' User entered '30 Sep 2020 12:04'	System	30 Sep 2020 18:04:37
	System	30 Sep 2020 18:04:37



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 4'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:53', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ffed9f59-0751-4d49-aae0-bf68826f2091'	System	01 Oct 2020 19:00:12
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 19:00:12

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:56', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ffed9f59-0751-4d49-aae0-bf68826f2091' User entered 'No (N)'	System	01 Oct 2020 19:00:12
	System	01 Oct 2020 19:00:12

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T12:59:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ffed9f59-0751-4d49-aae0-bf68826f2091' User entered 'No (N)'	System	01 Oct 2020 19:00:12
	System	01 Oct 2020 19:00:12

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:02', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ffed9f59-0751-4d49-aae0-bf68826f2091'	System	01 Oct 2020 19:00:12
User entered 'None (1)'	System	01 Oct 2020 19:00:12

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'ffed9f59-0751-4d49-aae0-bf68826f2091' User entered '01 Oct 2020 13:00'	System	01 Oct 2020 19:00:12
	System	01 Oct 2020 19:00:12



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 5'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1571bfca-ddd0-4c22-8115-dadcde66c25e'	System	02 Oct 2020 19:34:33
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 19:34:33

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:15', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1571bfca-ddd0-4c22-8115-dadcde66c25e' User entered 'No (N)'	System	02 Oct 2020 19:34:33
	System	02 Oct 2020 19:34:33

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1571bfca-ddd0-4c22-8115-dadcde66c25e' User entered 'No (N)'	System	02 Oct 2020 19:34:33
	System	02 Oct 2020 19:34:33

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1571bfca-ddd0-4c22-8115-dadcde66c25e' User entered 'None (1)'	System	02 Oct 2020 19:34:33
	System	02 Oct 2020 19:34:33

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:26', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1571bfca-ddd0-4c22-8115-dadcde66c25e' User entered '02 Oct 2020 13:34'	System	02 Oct 2020 19:34:33
	System	02 Oct 2020 19:34:33



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 6'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:37', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8511cf04-6e33-411d-af34-c33abad27546'	System	03 Oct 2020 18:36:52
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 18:36:52

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8511cf04-6e33-411d-af34-c33abad27546' User entered 'No (N)'	System	03 Oct 2020 18:36:52
	System	03 Oct 2020 18:36:52

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8511cf04-6e33-411d-af34-c33abad27546' User entered 'No (N)'	System	03 Oct 2020 18:36:52
	System	03 Oct 2020 18:36:52

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:46', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8511cf04-6e33-411d-af34-c33abad27546'	System	03 Oct 2020 18:36:52
User entered 'None (1)'	System	03 Oct 2020 18:36:52

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:36:50', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '8511cf04-6e33-411d-af34-c33abad27546' User entered '03 Oct 2020 12:36'	System	03 Oct 2020 18:36:52
	System	03 Oct 2020 18:36:52



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 7'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd41a1194-d1b0-49b2-b5bf-371c37496d6d' User entered 'None (1)'	System	04 Oct 2020 18:49:39
	System	04 Oct 2020 18:49:39

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd41a1194-d1b0-49b2-b5bf-371c37496d6d' User entered 'No (N)'	System	04 Oct 2020 18:49:39
	System	04 Oct 2020 18:49:39

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd41a1194-d1b0-49b2-b5bf-371c37496d6d' User entered 'No (N)'	System	04 Oct 2020 18:49:39
	System	04 Oct 2020 18:49:39

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:33', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd41a1194-d1b0-49b2-b5bf-371c37496d6d' User entered 'None (1)'	System	04 Oct 2020 18:49:39
	System	04 Oct 2020 18:49:39

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:37', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd41a1194-d1b0-49b2-b5bf-371c37496d6d' User entered '04 Oct 2020 12:49'	System	04 Oct 2020 18:49:39
	System	04 Oct 2020 18:49:39



US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:31', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'None (0)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:36', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'None (0)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'None (0)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'None (0)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:50', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'None (0)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:05:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'None (0)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:06:01', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered 'No (N)'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-28T12:06:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0c4f614c-71d7-41da-beed-4af75d39c83a' User entered '28 Sep 2020 12:06'	System	28 Sep 2020 18:06:09
	System	28 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'None (0)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'None (0)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:14', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'None (0)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:20', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'None (0)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:23', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'None (0)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'None (0)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:30', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered 'No (N)'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T08:48:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '0cdeed76-ae50-42f4-ae5-75e438800d62' User entered '29 Sep 2020 08:48'	System	29 Sep 2020 14:48:37
	System	29 Sep 2020 14:48:37

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 17:39:35



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 2'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:28', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc'	System	29 Sep 2020 18:06:09
User entered 'No interference with activity (1)'	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:33', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc'	System	29 Sep 2020 18:06:09
User entered 'No interference with activity (1)'	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:38', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc' User entered 'None (0)'	System	29 Sep 2020 18:06:09
	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:48', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc'	System	29 Sep 2020 18:06:09
User entered 'No interference with activity (1)'	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc' User entered 'None (0)'	System	29 Sep 2020 18:06:09
	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:05:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc' User entered 'None (0)'	System	29 Sep 2020 18:06:09
	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:06:03', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc' User entered 'No (N)'	System	29 Sep 2020 18:06:09
	System	29 Sep 2020 18:06:09



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-29T12:06:08', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '52993356-fcad-49ac-a73e-585f6f886cdc' User entered '29 Sep 2020 12:06'	System	29 Sep 2020 18:06:09
	System	29 Sep 2020 18:06:09

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 3'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:41', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20'	System	30 Sep 2020 18:05:13
User entered 'No interference with activity (1)'	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:47', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20'	System	30 Sep 2020 18:05:13
User entered 'No interference with activity (1)'	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:51', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20' User entered 'None (0)'	System	30 Sep 2020 18:05:13
	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:57', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20' User entered 'None (0)'	System	30 Sep 2020 18:05:13
	System	30 Sep 2020 18:05:13



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:04:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20' User entered 'None (0)'	System	30 Sep 2020 18:05:13
	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:05:02', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20' User entered 'None (0)'	System	30 Sep 2020 18:05:13
	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:05:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20'	System	30 Sep 2020 18:05:13
User entered 'No (N)'	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-09-30T12:05:10', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '714e6812-1421-4e46-8508-521d73da1c20' User entered '30 Sep 2020 12:05'	System	30 Sep 2020 18:05:13
	System	30 Sep 2020 18:05:13

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 4'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:14', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'None (0)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'None (0)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:27', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'None (0)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:30', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'None (0)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:39', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'None (0)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:43', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'None (0)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:49', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered 'No (N)'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-01T13:00:53', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '1cbb49b2-bf40-445c-b14c-6d9fdbd6614c' User entered '01 Oct 2020 13:00'	System	01 Oct 2020 19:01:00
	System	01 Oct 2020 19:01:00

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 17:39:35



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 5'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4'	System	02 Oct 2020 19:35:10
User entered 'No interference with activity (1)'	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:44', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4'	System	02 Oct 2020 19:35:10
User entered 'No interference with activity (1)'	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:46', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4' User entered 'None (0)'	System	02 Oct 2020 19:35:10
	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4'	System	02 Oct 2020 19:35:10
User entered 'No interference with activity (1)'	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:55', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4' User entered 'None (0)'	System	02 Oct 2020 19:35:10
	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:34:59', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4' User entered 'None (0)'	System	02 Oct 2020 19:35:10
	System	02 Oct 2020 19:35:10



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:35:04', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4' User entered 'No (N)'	System	02 Oct 2020 19:35:10
	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-02T13:35:07', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '366411bf-fc5d-4538-a3f4-32a86c4f45d4' User entered '02 Oct 2020 13:35'	System	02 Oct 2020 19:35:10
	System	02 Oct 2020 19:35:10

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 6'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:02', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'None (0)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:08', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'None (0)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:11', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'None (0)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:16', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'None (0)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:22', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'None (0)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:24', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'None (0)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:29', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered 'No (N)'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-03T12:37:33', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd6e56781-f8e9-4ec6-861e-d07f746b339f' User entered '03 Oct 2020 12:37'	System	03 Oct 2020 18:37:36
	System	03 Oct 2020 18:37:36

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	28 Sep 2020 17:39:35
User entered 'Day 7'	System	28 Sep 2020 17:39:35



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:44', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'None (0)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:52', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'None (0)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:49:56', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'None (0)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:50:00', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'None (0)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:50:03', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'None (0)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:50:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'None (0)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:50:10', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered 'No (N)'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-04T12:50:15', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '61c18183-9bff-40c3-af4f-2cae6326f414' User entered '04 Oct 2020 12:50'	System	04 Oct 2020 18:50:19
	System	04 Oct 2020 18:50:19



US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 17:39:35

US3892033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:20:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 17:39:35

US3892033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:27:01

US3892033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:27:01

US3892033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:27:01

US3892033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:27:01

US3892033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:27:06

**US3892033**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	05 Oct 2020 20:27:06



US3892033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:15

US3892033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:15

US3892033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:15

US3892033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:15

US3892033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:20

**US3892033**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	19 Oct 2020 21:39:20

US3892033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:34

US3892033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:34



US3892033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:34

US3892033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:34

US3892033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:39:38

US3892033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	19 Oct 2020 21:39:38

US3892033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:19

**US3892033**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:19

US3892033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:19

**US3892033**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:20:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'VISIT3'	System	26 Oct 2020 23:18:19



US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '10:57'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '26 Oct 2020 10:57'	System	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '97.3' F	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '71'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57



US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'bpm'	System	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '16'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'breaths/min'	System	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '131'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '60'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'mmHg'	System	26 Oct 2020 23:18:57

US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:19:08

US3892033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:19:08

US3892033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:19:33

US3892033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:19:33

US3892033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '11:26'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:19:33

US3892033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '26 Oct 2020 11:26'	System	26 Oct 2020 23:19:33

US3892033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:19:40



**US3892033**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	26 Oct 2020 23:19:40

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 64'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-31T08:10:06', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '134670cc-8713-4aa6-ae56-1dd90c83cdfd' User entered 'No (N)'	System	31 Oct 2020 14:10:28
	System	31 Oct 2020 14:10:28

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-31T08:10:17', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '134670cc-8713-4aa6-ae56-1dd90c83cdfd'	System	31 Oct 2020 14:10:28
User entered 'No (N)'	System	31 Oct 2020 14:10:28

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-10-31T08:10:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '134670cc-8713-4aa6-ae56-1dd90c83cdfd' User entered '31 Oct 2020 08:10:25'	System	31 Oct 2020 14:10:28
	System	31 Oct 2020 14:10:28

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 71'	System	31 Aug 2020 20:36:00



US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-11-07T01:16:18', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd3c89c4b-127a-4ca2-a108-b475f9f92bb3' User entered 'No (N)'	System	07 Nov 2020 08:16:38
	System	07 Nov 2020 08:16:38

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-11-07T01:16:26', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd3c89c4b-127a-4ca2-a108-b475f9f92bb3'	System	07 Nov 2020 08:16:38
User entered 'No (N)'	System	07 Nov 2020 08:16:38

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-11-07T01:16:34', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'd3c89c4b-127a-4ca2-a108-b475f9f92bb3' User entered '07 Nov 2020 01:16:34'	System	07 Nov 2020 08:16:38
	System	07 Nov 2020 08:16:38

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered 'Day 78'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-11-14T01:14:20', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '42f7595a-0805-4a06-9131-0ba919f37fec' User entered 'No (N)'	System	14 Nov 2020 08:14:44
	System	14 Nov 2020 08:14:44

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-11-14T01:14:30', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '42f7595a-0805-4a06-9131-0ba919f37fec' User entered 'No (N)'	System	14 Nov 2020 08:14:44
	System	14 Nov 2020 08:14:44



US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (41B04198-9EBF-4E76-B241-687E57A136F3)', Time: '2020-11-14T01:14:40', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: '42f7595a-0805-4a06-9131-0ba919f37fec' User entered '14 Nov 2020 01:14:40'	System	14 Nov 2020 08:14:44
	System	14 Nov 2020 08:14:44

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 20:36:00

US3892033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:52
Data entry locked.	System	31 Aug 2020 20:36:00
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 20:36:00

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:04:14



US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:04:14

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50

**US3892033**

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

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**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:04:14



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F72E7B32-3427-4E2A-9761-7D37192C8FF1)', Time: '2020-12-17T09:39:25', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a922a1f4-761c-4f25-8047-b63d53aa28d2'	System	17 Dec 2020 16:39:37
User entered 'No (N)'	System	17 Dec 2020 16:39:37

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F72E7B32-3427-4E2A-9761-7D37192C8FF1)', Time: '2020-12-17T09:39:29', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a922a1f4-761c-4f25-8047-b63d53aa28d2'	System	17 Dec 2020 16:39:37
User entered 'No (N)'	System	17 Dec 2020 16:39:37

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F72E7B32-3427-4E2A-9761-7D37192C8FF1)', Time: '2020-12-17T09:39:33', User OID: 'PatientReportedOutcome (US3892033)', ODM File OID: 'a922a1f4-761c-4f25-8047-b63d53aa28d2' User entered '17 Dec 2020 09:39:33'	System	17 Dec 2020 16:39:37
	System	17 Dec 2020 16:39:37

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:04:14



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:04:14

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Please 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) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:04:14

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:04:14



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:04:14

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[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)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Please 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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:04:14

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Please 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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:04:14



**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:04:14

US3892033

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50



US3892033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:41

[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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

Please 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) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:04:14

**US3892033**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:20:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:04:14
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:04:14

US3892033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Nov 2020 22:27:15

US3892033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 08:00:05
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Visit performed out of window. More than three attempts made inside the window, however without success. Subject returned contacts and at CRA's instruction. Visit carried out.' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	18 Dec 2020 00:37:24
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Dec 2020 00:25:49
User entered '16 Dec 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	18 Dec 2020 00:25:49
User entered '25 Nov 2020'	Andryelle Toledo (b) (4) (b) (4)	25 Nov 2020 22:27:15

US3892033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	18 Dec 2020 00:25:49
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Andryelle Toledo (b) (4)	25 Nov 2020 22:27:15
	(b) (4)	



US3892033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	18 Dec 2020 00:25:49
User entered 'Several attempts to contact the subject were unsuccessful.'	(b) (4)	
	Andryelle Toledo (b) (4)	25 Nov 2020 22:27:15
	(b) (4)	

US3892033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Nov 2020 22:27:19

**US3892033**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	25 Nov 2020 22:27:19

**US3892033**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:20:41**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:13:05
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 01:16:09

US3892033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:13:05
User entered '28 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 01:16:09

US3892033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:13:05
User entered 'Contact Made (CONTACT MADE)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 01:16:09

US3892033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:13:05
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 01:16:09

US3892033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:13:18
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 01:16:14



**US3892033**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	29 Dec 2020 01:16:14

US3892033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:48:18

US3892033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '25 Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:48:18

US3892033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:48:18

US3892033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:48:18

US3892033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:48:23

**US3892033**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 10:20:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	28 Jan 2021 20:48:23

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User closed query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:31:05
Query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'Subject was discontinued during Am.#6. Subject had SAE event reported, after subject has discharged from hospital subject reported received Pfizer vaccine. Sponsor requested ET and subject was unblinded. Date of update ICF is not applicable, neither N/A option' (Site from DM).	Andryelle Toledo (b) (4)	07 Apr 2021 19:00:37
User opened query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:47:47
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 05:34:27
Query 'Data is required. Please complete.' answered with 'Subject did not sign new ICF.' (Site from System).	Andryelle Toledo (b) (4)	01 Mar 2021 22:18:44
Amendment Manager: User opened query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 18:29:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 12:57:57



US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'Subject did not sign new ICF. Subject is early termination - Protocol Violation.' (Site from System).	Andryelle Toledo (b) (4)	28 Jan 2021 20:47:21
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 20:45:55
User entered empty.	Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:49
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Mar 2021 22:10:54
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:05:29

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:49
User closed query 'Kindly update EDC. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:44:05
Query 'Kindly update EDC. ' answered with 'Update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	31 Mar 2021 22:11:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andryelle Toledo (b) (4) (b) (4)	31 Mar 2021 22:10:54
User opened query 'Kindly update EDC. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 16:48:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:05:29

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '27 Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'mRNA-1273 (mRNA-1273)'	Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'mRNA-1273 (mRNA-1273)'	Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'mRNA-1273 (mRNA-1273)'	Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55



US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Jan 2021 20:45:55

US3892033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:20:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Jan 2021 20:45:55

US3892033

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:20:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE and HEADACHE persist beyond Day 7 (start date: Day 8; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:27:56
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 11 on 10SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:27:54
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE and HEADACHE persist beyond Day 7 (start date: Day 8; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 19:10:13
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 11 on 10SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 19:10:08
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE and HEADACHE persist beyond Day 7 (start date: Day 8; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 02:47:56

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:20:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 11 on 10SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 02:47:50
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:28
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	28 Dec 2020 23:40:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:44
User entered 'USA-US209-2020-mRNA-1273-P301000002'	System	29 Dec 2020 16:41:38
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 16:41:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Subarachnoid haemorrhage, LLT: Subarachnoid hemorrhage - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 17:46:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 17:46:19
Data point term sent to Coder	System	29 Dec 2020 17:45:29
Coding entries removed.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:44:29
User entered 'Subarachnoid hemorrhage' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:44:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Head injury, LLT: Head injury - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 23:55:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 23:55:32
Data point term sent to Coder	System	28 Dec 2020 23:54:11
User entered 'Head Trauma'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

US3892033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:09:02
DataPoint Un-verified.	Leslie Iverson (b) (4)	27 Jan 2021 15:04:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Leslie Iverson (b) (4)	27 Jan 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:09:04
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:10:57
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Hemorrhage stopped as of CT on 22DEC2020. Blood in subarachnoid space was sequelae.' (Site from Safety).	Leslie Iverson (b) (4)	27 Jan 2021 15:04:51
DataPoint Un-verified.	Leslie Iverson (b) (4)	27 Jan 2021 15:04:05
User entered '22 Dec 2020' reason for change: New Information	Leslie Iverson (b) (4)	27 Jan 2021 15:04:05
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:26:44
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:49
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:51:56
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41



**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:20:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:44:20
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'I sent fax with medical records today 21 Jan. 2021' (Site from Safety).	Andryelle Toledo (b) (4) (b) (4)	22 Jan 2021 01:31:29
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:52:53
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)	30 Dec 2020 11:41:56
User closed query 'PER CDM: Re-Query: As per previous response it was reported as 'requested for medical records'. However, request you please keep this query open until site get medical records and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 11:41:53
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 'update' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:45:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'PER CDM: Re-Query: As per previous response it was reported as 'requested for medical records'. However, request you please keep this query open until site get medical records and data recorded as appropriate. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	29 Dec 2020 17:45:38
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	29 Dec 2020 17:44:29
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'requested for medical records'. However, request you please keep this query open until site get medical records and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:21:52
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) (6)	29 Dec 2020 08:21:45
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 'I requested medical records today 28 Dec. 2020 to complete Hospital Admission Date' (Site from System).	Andryelle Toledo (b) (4)	29 Dec 2020 01:15:24
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	28 Dec 2020 23:53:41
User entered 'I'	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	29 Dec 2020 17:44:29
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '22 Dec 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	29 Dec 2020 17:44:29
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41



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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:49
Signature has been broken.	(b) (4)	
	Andryelle Toledo (b) (4)	09 Apr 2021 15:56:41
User signature succeeded.	(b) (4)	
	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 16:09:15
User entered '0' reason for change: Data Entry Error	Leslie Iverson (b) (4)	27 Jan 2021 15:05:43
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Jan 2021 15:05:16
DataPoint Un-verified.	Leslie Iverson (b) (4)	27 Jan 2021 15:05:16
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Leslie Iverson (b) (4)	27 Jan 2021 15:05:16
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Jan 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:06:19
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #12 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:33:02
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #12 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	23 Feb 2021 16:03:56
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	23 Feb 2021 16:03:31
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	23 Feb 2021 16:03:31
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #12 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:18:16
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:09:17
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:54:43
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' answered with 'CT scan was done to follow condition.' (Site from DM).	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:06:02
DataPoint Un-verified.	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:04:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Leslie Iverson (b) (4)	27 Jan 2021 15:04:05
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 11:10:08
	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '1'	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:37:31
User closed query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF are diagnostic. Only therapeutic procedures are acceptable for this field to be ticked. Update and reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:24:03
Query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF are diagnostic. Only therapeutic procedures are acceptable for this field to be ticked. Update and reconcile as appropriate. Otherwise, clarify.' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	23 Mar 2021 15:09:42
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	23 Mar 2021 15:09:24
Signature has been broken.	Andryelle Toledo (b) (4) (b) (4)	23 Mar 2021 15:09:24
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	23 Mar 2021 15:09:24
User opened query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF are diagnostic. Only therapeutic procedures are acceptable for this field to be ticked. Update and reconcile as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:05:34
User signature succeeded.	Michael Adams (b) (4) (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:33:06

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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'The procedures reported is correct, and it was the procedure realized during hospitalization and confirmed with medical records. ' (Site from DM).	Andryelle Toledo (b) (4)	23 Feb 2021 16:07:21
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:18:11
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:09:20
DataPoint Un-verified.	Leslie Iverson (b) (4)	27 Jan 2021 15:05:43
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	27 Jan 2021 15:05:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:09:24
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:11:03
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Hemorrhage stopped as of CT on 22DEC2020. Sequelae is blood in subarachnoid space.' (Site from Safety).	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:06:45
DataPoint Un-verified.	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:04:05
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:52:11
User closed query 'PER CDM: RE-QUERY: Response noted. However, as event is ongoing kindly consider checking the appropriate option from the list available (for example Not recovered/resolved or recovering/resolving). Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 11:47:20
Query 'PER CDM: RE-QUERY: Response noted. However, as event is ongoing kindly consider checking the appropriate option from the list available (for example Not recovered/resolved or recovering/resolving). Please review and update as appropriate. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:54:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	29 Dec 2020 17:54:25
User opened query 'PER CDM: RE-QUERY: Response noted. However, as event is ongoing kindly consider checking the appropriate option from the list available (for example Not recovered/resolved or recovering/resolving). Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:23:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 08:22:55
Query 'Data is required. Please complete.' answered with 'Ongoing, please see note' (Site from System).	Andryelle Toledo (b) (4)	29 Dec 2020 01:15:35
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 23:53:41
User entered empty.	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:09:30
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	27 Jan 2021 15:07:10
DataPoint Un-verified.	Leslie Iverson (b) (4)	27 Jan 2021 15:07:10
User entered 'Blood in subarachnoid space.' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	27 Jan 2021 15:07:10
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
	System	27 Jan 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4)	28 Dec 2020 23:53:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'PV Query: Please provide the date the subject was discharged from the rehabilitation facility.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:11:06
Query 'PV Query: Please provide the date the subject was discharged from the rehabilitation facility.' answered with 'Subject was discharged from rehabilitation facility on 21JAN2021.' (Site from Safety).	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:07:46
User closed query 'PV Query: Did the subject receive any additional 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)	06 Jan 2021 18:10:11
User closed query 'PV Query: Please provide relevant diagnostic and laboratory testing used to diagnose/monitor the event including any confirmation of trauma to head from fall. Please provide the test with date performed and results.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:10:08
User closed query 'PV Query: Please assess if "fall" met AE SAE reporting criteria. If so please report, if not please state as such.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:10:03
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)	06 Jan 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Did the subject receive any additional 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 surgical or medical intervention provided other than pain control and general wound care.' (Site from Safety).	Leslie Iverson (b) (4)	05 Jan 2021 19:06:05
Query 'PV Query: Please provide relevant diagnostic and laboratory testing used to diagnose/ monitor the event including any confirmation of trauma to head from fall. Please provide the test with date performed and results.' answered with '12/20/2020 CT Brain: 1. Small volume of subarachnoid hemorrhage along the left convexity and within the left perimesencephalic cistern. 2. Left scalp subcutaneous hematoma. 3. No significant intracranial mass effect. CT Brain 12/21/2020 1. Unchanged focal areas of subarachnoid hemorrhage, post-traumatic. Prominent left parietal scalp hemorrhage, otherwise negative. ' (Site from Safety).	Leslie Iverson (b) (4)	05 Jan 2021 17:14:58
Query 'PV Query: Please assess if "fall" met AE SAE reporting criteria. If so please report, if not please state as such.' answered with 'The injuries sustained in the fall led to the emergency room visit. The subarachnoid hemorrhage led to hospital admission. ' (Site from Safety).	Leslie Iverson (b) (4)	05 Jan 2021 17:09:29
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'SARS CoV-2 by PCR done on 12/20/2020 while inpatient, result was "not detected."' (Site from Safety).	Leslie Iverson (b) (4)	05 Jan 2021 17:07:28
User opened query 'PV Query: Please provide the date the subject was discharged from the rehabilitation facility.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:53:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject receive any additional 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)	05 Jan 2021 16:53:29
User opened query 'PV Query: Please provide relevant diagnostic and laboratory testing used to diagnose/ monitor the event including any confirmation of trauma to head from fall. Please provide the test with date performed and results.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:53:20
User opened query 'PV Query: Please assess if "fall" met AE SAE reporting criteria. If so please report, if not please state as such.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:53:12
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:51:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Dec 2020 00:09:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Dec 2020 00:09:55
User entered 'Subject contacted for monthly Safety Call today and he reported he is at rehabilitation center currently. He reports falling on ice/snow while going to a church activity on 20 Dec. 2020. He was evaluated at hospital admitted and transferred to rehab 'facility' later in the week where he remains. He anticipates possible discharge home tomorrow (29 Dec. 2020). He did not have many details regarding his condition or treatment only that he had started "Lortab". He asked Dr. Adams to request records to learn more He denies any illness or COVID-19 since last study contact.' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Dec 2020 23:53:41
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	28 Dec 2020 23:53:41

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	28 Dec 2020 23:53:41

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	28 Dec 2020 23:53:41

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:20:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Clavicle fracture, LLT: Clavicle fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 20:58:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 20:58:27
Data point term sent to Coder	System	29 Dec 2020 17:58:44
User entered 'Left Clavicular Fracture'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:20
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:23
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:25
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:27
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 17:57:46



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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:33:36
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'It is ongoing' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:16:59
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:18:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	28 Jan 2021 20:55:32
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	28 Jan 2021 20:55:01
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:28
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	28 Jan 2021 20:55:32
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Jan 2021 20:55:32
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 20:55:32
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	28 Jan 2021 20:55:01
User entered '26 Jan 2021' reason for change: Data Entry Error	System	28 Jan 2021 20:55:01
DataPoint Un-verified.	Andryelle Toledo (b) (4)	05 Jan 2021 20:07:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 17:57:46

US3892033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:32
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:20:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 17:57:46

US3892033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

US3892033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:38
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:41
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:45
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:46
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:48
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:49
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:51
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:56
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Jan 2021 16:57:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Dec 2020 17:57:46
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:08:00
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '1' reason for change: New Information	Leslie Iverson (b) (4)	05 Jan 2021 16:57:21
User entered '0'	Andryelle Toledo (b) (4)	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR-RQ: Response noted. However, please note that X-ray is a diagnostic procedure. Please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc ecrf to include a therapeutic procedure.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 09:35:33
Query 'Per DM CLR-RQ: Response noted. However, please note that X-ray is a diagnostic procedure. Please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc ecrf to include a therapeutic procedure.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 18:24:19
User entered '0' reason for change: New Information	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 18:24:13
User opened query 'Per DM CLR-RQ: Response noted. However, please note that X-ray is a diagnostic procedure. Please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc ecrf to include a therapeutic procedure.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:34:01
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:16:24
Query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field.' answered with 'X-Ray was the concomitant procedure' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	01 Feb 2021 17:09:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	30 Jan 2021 03:45:50
	(b) (4), (b) (6)	05 Jan 2021 20:08:02
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '1' reason for change: New Information	Leslie Iverson (b) (4)	05 Jan 2021 16:57:21
User entered '0'	Andryelle Toledo (b) (4)	29 Dec 2020 17:57:46

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 20:55:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Andryelle Toledo (b) (4)	28 Jan 2021 20:55:01
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:08:04
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 17:57:46
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 17:57:46
	(b) (4)	



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:07
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:57:46

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	29 Dec 2020 17:57:46

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:11
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:00:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:00:19
Data point term sent to Coder	System	29 Dec 2020 17:59:44
User entered 'Chronic Kidney Disease Stage III'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:13
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:14
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:17
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 20:56:34
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 20:56:08
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:08:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	28 Jan 2021 20:56:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Jan 2021 20:56:34
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 20:56:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	28 Jan 2021 20:56:08
User entered '26 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 20:56:08
DataPoint Un-verified.	(b) (4)	05 Jan 2021 20:08:23
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 17:59:26
	(b) (4)	

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:25
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26



**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:20:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 17:59:26

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:28
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:31
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:33
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

US3892033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:38
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:41
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:47
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:49
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:50
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:55
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 20:56:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 20:56:08
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 17:59:26
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 17:59:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:00
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 17:59:26

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	29 Dec 2020 17:59:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	29 Dec 2020 17:59:26



**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:06
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User coded data point as SOC: Vascular disorders, HLTG: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 12:12:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 12:12:29
Data point term sent to Coder	System	29 Dec 2020 21:57:10
Coding entries removed.	Leslie Iverson (b) (4) (b) (4)	29 Dec 2020 21:56:40
User entered 'RIGHT LEG HEMATOMA' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	29 Dec 2020 21:56:40
User coded data point as SOC: Vascular disorders, HLTG: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 20:57:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 20:57:26
Data point term sent to Coder	System	29 Dec 2020 18:00:45
User entered 'Leg Hematoma'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:08
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:10
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:12
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:13
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 15:33:26
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	29 Dec 2020 18:00:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '21 Dec 2020' reason for change: New Information	(b) (4)	27 Jan 2021 15:33:26
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 18:00:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:20
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:26
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:28
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:29
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:31
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:33
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:38
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15



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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:00:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:24
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:15
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:45
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:00:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:24
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:15
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:47
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:00:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:24
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:15
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	27 Jan 2021 15:33:26
User entered '0' reason for change: Data Entry Error	Leslie Iverson (b) (4)	27 Jan 2021 15:33:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:48
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	05 Jan 2021 17:23:07
User entered '1'	Andryelle Toledo (b) (4)	29 Dec 2020 18:00:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:50
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:18:07
Query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' answered with 'Debridement R Leg hematoma was the concomitant procedure' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	01 Feb 2021 17:11:10
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 03:47:58
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '1' reason for change: New Information	Leslie Iverson (b) (4)	05 Jan 2021 17:23:07
User entered '0'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:00:15

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 15:33:26
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	27 Jan 2021 15:33:26
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:00:15
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 18:00:15
	(b) (4)	



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'Post-Debridement Wound R Leg' reason for change: New Information	System	27 Jan 2021 15:34:02
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	Leslie Iverson (b) (4)	27 Jan 2021 15:34:02
DataPoint Un-verified.	(b) (4)	
DataPoint Verified.	System	27 Jan 2021 15:33:26
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 20:09:55
	(b) (4), (b) (6)	05 Jan 2021 20:07:08
	Andryelle Toledo (b) (4)	29 Dec 2020 18:00:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:49
Signature has been broken.	(b) (4)	09 Apr 2021 16:01:04
User entered 'Leg hematoma occurred due to trauma but did not lead to or prolong hospitalization. Subject reports that the hematoma is healing. Changed end date to include complication of hematoma per sponsor query. Wound had not resolved at time of early termination.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	09 Apr 2021 16:01:04
User signature succeeded.	(b) (4)	
DataPoint Un-verified.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:09:56
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 18:00:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	29 Dec 2020 18:00:15

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:20:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:01
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:17:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:17:37
Data point term sent to Coder	System	29 Dec 2020 18:01:46
User entered 'Thyroid Nodule'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:03
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Form: Adverse Events (5)

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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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:07
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:12
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:20:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:14
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11



US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:10:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andryelle Toledo (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:23
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:26
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:27
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:29
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

US3892033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:37
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:01:21
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:21
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:11
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:01:21
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:21
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:11
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:41
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 18:01:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:21
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:11
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:42
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:44
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'I'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:45
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 21:04:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	28 Jan 2021 21:04:56
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:10:47
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:01:11
User entered empty.	Andryelle Toledo (b) (4)	29 Dec 2020 18:01:11
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:49
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:51
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:01:11

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	29 Dec 2020 18:01:11

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	29 Dec 2020 18:01:11



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:55
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Subcutaneous haematoma, LLT: Subcutaneous hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:39:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:39:29
Data point term sent to Coder	System	05 Jan 2021 17:24:58
User entered 'Left Scalp Subcutaneous Hematoma'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

US3892033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:00
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:02
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:04
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:33:46
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'It is ongoing. Per PA: Subject contacted, hematoma is smaller but persists.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:18:11
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:19:25
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:06
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Yes (Y)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:08
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 10:20:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:24:21

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:10
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:14
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21



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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:16
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:17
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:20
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:25
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:26
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21



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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:28
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:24:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:24:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:32
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:24:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:32
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:24:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:24:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	05 Jan 2021 17:24:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Jan 2021 17:24:21
	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:24:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:24:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:32
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:24:21
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	25 Feb 2021 19:10:41
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:11:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:37
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '0'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'Update' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:33:56
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 19:10:46
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	Andryelle Toledo (b) (4)	25 Feb 2021 19:10:41
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	20 Feb 2021 01:20:01
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered '1'	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 21:05:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Andryelle Toledo (b) (4)	28 Jan 2021 21:05:16
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:24:21
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21
	(b) (4)	



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:42
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:24:21

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:07:08
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:24:21

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	05 Jan 2021 17:24:21

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	05 Jan 2021 17:24:21

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Folder: Adverse Events

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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**Folder: Adverse Events**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 16:17:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 16:17:09
Data point term sent to Coder	System	27 Jan 2021 15:37:03
User entered 'Fall from Ground Level'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48



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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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Folder: Adverse Events

Form: Adverse Events (8)

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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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	27 Jan 2021 15:36:48

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48



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**Generated On: 10 Jun 2021 10:20:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	27 Jan 2021 15:36:48

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

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Folder: Adverse Events

Form: Adverse Events (8)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48



US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

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Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'None (NONE)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'I'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Subject was transported to Emergency room after fall. The fall itself did not lead to or prolong hospitalization.'	Leslie Iverson (b) (4)	27 Jan 2021 15:36:48

US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	27 Jan 2021 15:36:48

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered 'I'	System	27 Jan 2021 15:36:48



US3892033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 10:20:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:36:56
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'No. It was reported in eDiary after vaccination. AE was opened because event extended more than 7 days after vaccination.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	29 Mar 2021 18:23:17
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:30:21
User signature succeeded.	Michael Adams (b) (4) (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:09:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:09:59
Data point term sent to Coder	System	25 Feb 2021 19:08:44
User entered 'Fatigue'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '01 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:06:42
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:01
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 19:08:42
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	25 Feb 2021 19:08:42

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '09 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:06:40
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:05
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 19:08:42
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Related (RELATED)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
Signature has been broken.	(b) (4)	
	Andryelle Toledo (b) (4)	10 Mar 2021 22:46:40
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Mar 2021 22:46:40
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
	(b) (4)	
User entered '1'	Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
Signature has been broken.	Andryelle Toledo (b) (4)	10 Mar 2021 22:46:40
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Mar 2021 22:46:40
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	25 Feb 2021 19:08:42

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	25 Feb 2021 19:08:42

US3892033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:05:50

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:12:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:12:00
Data point term sent to Coder	System	25 Feb 2021 19:10:47
User entered 'Headache'	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48
	(b) (4)	

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48



US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '01 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:06:54
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:53
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 19:09:48
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	25 Feb 2021 19:09:48

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '11 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 13:06:56
Query 'Data is required. Please provide.' answered with 'Time is UNK' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:57
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 19:09:48
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48
	(b) (4)	



US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48
	(b) (4)	

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48



US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Related (RELATED)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48



US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'I'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '0'	Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	25 Feb 2021 19:09:48

US3892033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:20:41

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '0'	System	25 Feb 2021 19:09:48



**US3892033**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:20:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:00
User entered 'Yes (Y)'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:04:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 03:56:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:56:35
Data point term sent to Coder	System	01 Sep 2020 00:05:55
User entered 'Carvediolol'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'heart failure'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '10'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:11



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	29 Dec 2020 18:18:16
User entered 'Yes (Y)'	(b) (4)	
	chase Carnahan (b) (4)	01 Sep 2020 00:05:11
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	29 Dec 2020 18:18:16
User entered empty.	(b) (4)	
	chase Carnahan (b) (4)	01 Sep 2020 00:05:11
	(b) (4)	



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:05:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:05:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 00:06:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:06:35
Data point term sent to Coder	System	01 Sep 2020 00:05:55
User entered 'furosemide'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'heart failure'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '40'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:05:42

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:05:42

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:04:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:04:46
Data point term sent to Coder	System	01 Sep 2020 00:06:56
User entered 'finasteride'	chase Carnahan (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:11



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'urinary retention'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '5'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:06:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:06:11



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:55:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:55:38
Data point term sent to Coder Coding entries removed.	System Andryelle Toledo (b) (4)	20 Oct 2020 17:54:40 20 Oct 2020 17:54:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 00:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 00:07:40
Data point term sent to Coder User entered 'cymbalta'	System chase Carnahan (b) (4)	01 Sep 2020 00:06:59 01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'BIPOLAR Disorder' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	20 Oct 2020 17:54:34
User entered 'bipolar'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47
	(b) (4)	

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '60'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:47



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2010'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:06:47



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:06:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:06:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: OTHER DIURETICS, PRODUCT: ISOSORBIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 07:25:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:25:51
Data point term sent to Coder	System	01 Sep 2020 00:07:59
User entered 'isosorbide'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'heart failure'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '30'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:07:35



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:07:35

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:07:35

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:07:35

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:07:35

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 08:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:24:43
Data point term sent to Coder	System	01 Sep 2020 00:09:02
User entered 'potassium'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'heart failure'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:01:03
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'The correct unit is mEq. Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	30 Sep 2020 16:38:12
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:17:27
User entered '10'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:11



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	30 Sep 2020 16:38:24
User entered 'mg (mg)'	(b) (4)	
	chase Carnahan (b) (4)	01 Sep 2020 00:08:11
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mEq' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 16:38:24
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:11



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:08:11

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:08:11

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:57:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:57:53
Data point term sent to Coder	System	28 Sep 2020 19:47:51
Coding entries removed.	Andryelle Toledo (b) (4)	28 Sep 2020 19:47:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:53:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:53:45
Data point term sent to Coder	System	10 Sep 2020 22:35:01
User closed query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' (Site from System).	System	10 Sep 2020 22:34:04
Query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' answered with 'Acetaminophen, aspirin and caffeine. Update' (Site from System).	Andryelle Toledo (b) (4)	10 Sep 2020 22:34:04
Data point term sent to Coder	System	10 Sep 2020 22:34:00
User entered 'EXCEDRIN (acetaminophen, aspirin and caffeine)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Sep 2020 22:33:54

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' (Site from System). Data point term sent to Coder	Coder Import (b) (4) (b) (4)	01 Sep 2020 09:16:43
User entered 'excedrin'	System chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:09:02 01 Sep 2020 00:08:54



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please review the indication to include the specific location of OSTEOARTHRITIS (e.g. Left Knee, Right Hips, Generalized, etc.). Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:01:20
Query 'Per DM CLR: Please review the indication to include the specific location of OSTEOARTHRITIS (e.g. Left Knee, Right Hips, Generalized, etc.). Reconcile and update as appropriate. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:47:24
User entered 'GENERALIZED OSTEOARTHRITIS' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:47:19
User entered 'Generalize OSTEOARTHRITIS' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:47:13
User opened query 'Per DM CLR: Please review the indication to include the specific location of OSTEOARTHRITIS (e.g. Left Knee, Right Hips, Generalized, etc.). Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:18:22
User entered 'osteoarthritis'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'PER DM CLR: RE-QUERY: Response noted. However, kindly consider updating doses for all components in the combination drug. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 11:52:13
Query 'PER DM CLR: RE-QUERY: Response noted. However, kindly consider updating doses for all components in the combination drug. Thank you.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	20 Oct 2020 17:55:31
User entered '250-250-65' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	20 Oct 2020 17:55:24
User opened query 'PER DM CLR: RE-QUERY: Response noted. However, kindly consider updating doses for all components in the combination drug. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 17:51:28
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 17:51:28
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:47:00
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 19:46:40
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:18:39
User entered '500'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	20 Oct 2020 17:55:24
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	28 Sep 2020 19:46:40
User entered 'mg (mg)'	chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:54



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2018'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:08:54

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:08:54

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:08:54



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:08:54

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 00:10:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 00:10:42
Data point term sent to Coder	System	01 Sep 2020 00:10:05
User entered 'tylenol'	chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'headaches'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'update' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:02:11
User entered '650' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	30 Sep 2020 17:04:29
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
User entered '600'	(b) (4), (b) (6)	20 Sep 2020 15:19:44
	chase Carnahan (b) (4)	01 Sep 2020 00:09:41
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:09:41

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 1985'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:09:41

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:09:41



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:09:41

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:09:41

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	01 Sep 2020 00:09:41

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 06:57:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 06:57:15
Data point term sent to Coder Coding entries removed.	System Andryelle Toledo (b) (4)	25 Feb 2021 16:22:33 25 Feb 2021 16:22:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 02:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 02:09:37
Data point term sent to Coder User entered 'amiodarone'	System chase Carnahan (b) (4)	01 Sep 2020 00:11:06 01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:32:04
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Term. update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:22:39
User entered 'Intermittent atrial fibrillation' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:22:21
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 20:34:02
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:03:09
Query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Unknow type of Arrhythmia' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	20 Oct 2020 17:56:16
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:20:28
User entered 'arrhythmia'	chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '100'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'un UNK 2014'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) chase Carnahan (b) (4) (b) (4)	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Dec 2020 18:18:54
User entered 'Yes (Y)'	chase Carnahan (b) (4)	01 Sep 2020 00:10:19
	(b) (4)	



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	29 Dec 2020 18:18:54
User entered empty.	(b) (4)	
	chase Carnahan (b) (4)	01 Sep 2020 00:10:19
	(b) (4)	

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	01 Sep 2020 00:10:19

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	01 Sep 2020 00:10:19

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 23:22:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 23:22:25
Data point term sent to Coder	System	26 Oct 2020 23:21:27
User entered 'influenza Vaccine'	Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'influenza'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	29 Dec 2020 18:19:38
User entered '1'	(b) (4)	
	Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	29 Dec 2020 18:19:38
User entered 'Other (OTHER)'	(b) (4)	
	Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty; reason for change Data Entry Error	(b) (4)	29 Dec 2020 18:19:38
User entered 'dose'	Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once (ONCE)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '14 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '14 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:20:48

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	26 Oct 2020 23:20:48

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	26 Oct 2020 23:20:48

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	26 Oct 2020 23:20:48

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Mar 2021 23:02:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	10 Mar 2021 23:02:39
Data point term sent to Coder Coding entries removed.	System Andryelle Toledo (b) (4)	10 Mar 2021 22:46:23 10 Mar 2021 22:45:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 23:23:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	26 Oct 2020 23:23:27
Data point term sent to Coder User entered 'advil'	System Andryelle Toledo (b) (4)	26 Oct 2020 23:22:30 26 Oct 2020 23:21:36



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR-RQ: Response noted below. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm that "BODY ACHES DID NOT MEET AE REPORTING CRITERIA" in query response. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:30:40
User entered 'FAtigue' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Mar 2021 22:45:36
Query 'Per DM CLR-RQ: Response noted below. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm that "BODY ACHES DID NOT MEET AE REPORTING CRITERIA" in query response. Update as appropriate. Otherwise, clarify.' answered with 'AE was reported.' (Site from DM).	Andryelle Toledo (b) (4)	10 Mar 2021 22:45:05
User opened query 'Per DM CLR-RQ: Response noted below. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm that "BODY ACHES DID NOT MEET AE REPORTING CRITERIA" in query response. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:02:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:27:53
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'update dates, solicited event' (Site from DM).	Andryelle Toledo (b) (4)	28 Jan 2021 21:24:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:32:26
User entered 'body aches'	Andryelle Toledo (b) (4) (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '1500'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 21:23:54
User entered '10 Sep 2020'	Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	28 Jan 2021 21:23:54
User entered '13 Sep 2020'	(b) (4)	
	Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 21:24:30
User entered 'No (N)'	Andryelle Toledo (b) (4)	26 Oct 2020 23:21:36
	(b) (4)	

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	26 Oct 2020 23:21:36



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	26 Oct 2020 23:21:36

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	26 Oct 2020 23:21:36

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
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: LORTAB [HYDROCODONE BITARTRATE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 10:03:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Feb 2021 10:03:53
Data point term sent to Coder	System	28 Jan 2021 20:53:04
Coding entries removed.	Andryelle Toledo (b) (4)	28 Jan 2021 20:52:07
DataPoint Verified.	(b) (4)	05 Jan 2021 22:14:25
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: LORTAB [HYDROCODONE BITARTRATE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:28:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	05 Jan 2021 19:28:38
Data point term sent to Coder	System	05 Jan 2021 16:42:20
Coding entries removed.	Leslie Iverson (b) (4)	05 Jan 2021 16:41:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
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: LORTAB [HYDROCODONE BITARTRATE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 11:51:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 11:51:16
Data point term sent to Coder	System	29 Dec 2020 00:48:22
User entered 'Lortab'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:14:28
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:47:48
User closed query 'This should be separated out as 2 different indications. Kindly update. Thank you.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 20:39:12
Query 'This should be separated out as 2 different indications. Kindly update. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4)	28 Jan 2021 20:53:37
DataPoint Un-verified.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:52:07
User entered 'SUBARACHNOID HEMORRHAGE' reason for change: New Information	Andryelle Toledo (b) (4)	28 Jan 2021 20:52:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:14:29
User opened query 'This should be separated out as 2 different indications. Kindly update. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:13:01
User entered '1. Subarachnoid Hemorrhage 2. Left Clavicular Fracture' reason for change: New Information	Leslie Iverson (b) (4)	05 Jan 2021 16:41:21
User entered 'Head trauma'	Andryelle Toledo (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:14:31
User entered '5-325'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:14:32
User entered 'mg (mg)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:14:43
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:14:45
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:15:01
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:15:13
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:15:21
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:15:23
User entered '20 Dec 2020'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:15:24
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:07:58
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Un-verified.	(b) (4)	
	Andryelle Toledo (b) (4)	10 Mar 2021 22:53:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	10 Mar 2021 22:53:47
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:15:28
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	29 Dec 2020 00:47:33
	(b) (4)	



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:20:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:08:00
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
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) (4), (b) (6)	11 Mar 2021 18:30:59
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Mar 2021 22:53:47
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 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:53:42
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Mar 2021 22:53:33
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:53:33
User entered '22 Dec 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:53:33
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)	08 Mar 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:15:31
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 00:47:33

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:15:33
User entered 'No (N)'	Andryelle Toledo (b) (4)	29 Dec 2020 00:47:33

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 00:47:33

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 00:47:33

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	29 Dec 2020 00:47:33

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:15:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:15:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:15:19
Data point term sent to Coder	System	29 Dec 2020 18:13:59
User entered 'Atorvastatin'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
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)	26 Feb 2021 11:32:20
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 'Indication is in Medical History - ongoing' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:26:23
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)	03 Feb 2021 20:51:56
User entered 'Coronary artery disease'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:13:12



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '40'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:13:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:13:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:13:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	29 Dec 2020 18:13:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Dec 2020 18:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:17:38
Data point term sent to Coder	System	29 Dec 2020 18:16:00
User entered 'Carvedilol'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:15:21



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'heart failure'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '3.125'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'twice daily (BID)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:15:21

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '2'	System	29 Dec 2020 18:15:21

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:15:21



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	29 Dec 2020 18:15:21

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEART FAILURE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:32:32
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEART FAILURE should be recorded, and update con med indication or provide clarification. ' answered with 'There was no worsening of heart failure. Addition of hydralazine was due to hospital protocol/provider preference during admission for SAE of subarachnoid hemorrhage.' (Site from DM).	Leslie Iverson (b) (4) (b) (4)	25 Feb 2021 18:17:40
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEART FAILURE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 20:52:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:40:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:40:20
Data point term sent to Coder	System	29 Dec 2020 18:17:01
User entered 'Hydralazine'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Heart Failure'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '25'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'three times daily (TID)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:16:22



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '3'	System	29 Dec 2020 18:16:22

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:16:22

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	29 Dec 2020 18:16:22

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: this Con Med had dose increased on 20 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:32:41
Query 'Per DM CLR: this Con Med had dose increased on 20 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'There was no worsening of atrial fibrillation. Increased dose of amiodarone was due to hospital protocol/provider preference during admission for SAE of subarachnoid hemorrhage.' (Site from DM).	Leslie Iverson (b) (4) (b) (4)	25 Feb 2021 18:18:33
User opened query 'Per DM CLR: this Con Med had dose increased on 20 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:11:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:28:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:28:25
Data point term sent to Coder	System	29 Dec 2020 18:18:02
User entered 'Amiodarone'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Atrial Fibrillation'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '200'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:02

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:17:02

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:17:02

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	29 Dec 2020 18:17:02

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Dec 2020 18:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:18:18
Data point term sent to Coder	System	29 Dec 2020 18:18:02
User entered 'Levothyroxine'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Thyroid nodule'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:20:41**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '50'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:32:49
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:31:38
User entered 'ug (ug)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:31:33
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:12:25
User entered 'mg (mg)'	Andryelle Toledo (b) (4) (b) (4)	29 Dec 2020 18:17:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once daily (QD)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	29 Dec 2020 18:17:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:17:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	29 Dec 2020 18:17:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	29 Dec 2020 18:17:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:17:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:49:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:49:29
Data point term sent to Coder	System	05 Jan 2021 17:39:10
User entered 'Oxycodone'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:38:24



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:17:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:38:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:38:33
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:38:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:38:24
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:09
User entered 'Left clavicular fracture'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:13
User entered '5'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:14
User entered 'mg (mg)'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:16
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:18
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:20
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:22
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:23
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:25
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:33
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:39
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:17:41
User entered '22 Dec 2020'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:17:42
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:38:24

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:38:24



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:38:24

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:18:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:41:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:41:29
Data point term sent to Coder	System	05 Jan 2021 17:40:11
User entered 'Spironolactone'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:18:57
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:18:59
User entered 'Heart Failure'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:00
User entered '25'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:02
User entered 'mg (mg)'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:04
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:05
User entered 'once daily (QD)'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:19:07
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:39:26

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:08
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:10
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:12
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:14
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:16
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:17
User entered '22 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:19
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:39:26



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	05 Jan 2021 17:39:26

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '1'	System	05 Jan 2021 17:39:26

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '804 (804)'	System	05 Jan 2021 17:39:26

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:19:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:42:37
Data point term sent to Coder	System	05 Jan 2021 17:42:12
User entered 'Zofran'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:28
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:33
User entered 'Nausea prophylaxis'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:36
User entered '4'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:41
User entered 'mg (mg)'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:43
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:46
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:48
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:52
User entered 'Intravenous (INTRAVENOUS)'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:53
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:19:58
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:00
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:02
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:41:25



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:03
User entered '22 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:05
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:41:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:41:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:41:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:41:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:43:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:43:31
Data point term sent to Coder	System	05 Jan 2021 17:43:13
User entered 'Melatonin'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:19
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:22
User entered 'Insomnia prophylaxis'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:03



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:26
User entered '5'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:27
User entered 'mg (mg)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:29
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:31
User entered 'as needed (PRN)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:32
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:34
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:36
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:37
User entered '20 Dec 2020'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:03



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:39
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:41
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:43
User entered '22 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:20:44
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:03

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:43:03

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:43:03

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:43:03

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:47:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:47:30
Data point term sent to Coder	System	05 Jan 2021 17:45:14
Data point term sent to Coder	System	05 Jan 2021 17:44:13
User entered 'Docusate'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:58
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:20:59
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'Bowel prophylaxis' reason for change: Leslie Iverson	(b) (4)	05 Jan 2021 17:44:47
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:01
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered '283' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:04
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'mg (mg)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:06
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:10
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'as needed (PRN)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:12
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:15
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'Rectal (RECTAL)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:16
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:18
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Jan 2021 17:44:47
User entered '20 Dec 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 10:20:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:20
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:24
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:26
User entered '22 Dec 2020' reason for change: Data Entry Error	Leslie Iverson (b) (4)	05 Jan 2021 17:44:47
User entered empty.	(b) (4) Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:29
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:44:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:44:47
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:44:47
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:43:25
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:43:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:43:25

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:43:25



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:43:25

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:47:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:47:31
Data point term sent to Coder	System	05 Jan 2021 17:46:16
User entered 'Bisocodyl'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:40
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:42
User entered 'Bowel Prophylaxis'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:43
User entered '10'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:46
User entered 'mg (mg)'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:48
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:49
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:21:51
User entered empty.	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:52
User entered 'Rectal (RECTAL)'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:54
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:57
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:21:58
User entered '0'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:22:00
User entered 'No (N)'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:22:02
User entered '22 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Kindly ensure that line #22 on con med log (hydralazine and line #25 tylenol are added to con med page in EDC. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:09:52
Query 'Kindly ensure that line #22 on con med log (hydralazine and line #25 tylenol are added to con med page in EDC. Thank you.' answered with 'medications added, thank you' (Site from CRA).	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 16:58:48
User opened query 'Kindly ensure that line #22 on con med log (hydralazine and line #25 tylenol are added to con med page in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 22:23:47
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:22:04
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:45:31



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:45:31

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:45:31

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	05 Jan 2021 17:45:31

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HEART FAILURE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:31:26
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HEART FAILURE; update Con Med indication or provide clarification. ' answered with 'No worsening. Medication for Heart failure were adjusted during hospitalization but were per provider preference and not due to worsening. ' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:56:38
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HEART FAILURE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:06:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 23:43:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 23:43:11
Data point term sent to Coder	System	19 Jan 2021 16:56:48
User entered 'Hydralazine'	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Heart Failure'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '10'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Intravenous (INTRAVENOUS)'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '22 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 16:56:34

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	19 Jan 2021 16:56:34

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	19 Jan 2021 16:56:34

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	19 Jan 2021 16:56:34

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Jan 2021 17:00:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 17:00:07
Data point term sent to Coder	System	19 Jan 2021 16:58:49
User entered 'Tylenol'	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 16:58:20
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 16:58:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Jan 2021 16:58:12
	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12
	(b) (4)	

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'L clavicle fracture'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '1000'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '22 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 16:58:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	19 Jan 2021 16:58:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	19 Jan 2021 16:58:12

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	19 Jan 2021 16:58:12

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User closed query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 11:27:17
Query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly.' answered with 'Confirm no participation in different studies. Subject was in a rehab. after hospitalization, and because it was offering the vaccination to patients of his age, he was vaccinated. The subject did not inform the rehab center that he was participating in a study for the COVID-19 vaccine.' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 19:21:25
User opened query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:42:26
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) (b) (4)	01 Feb 2021 20:06:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:06:31
Data point term sent to Coder	System	27 Jan 2021 15:56:20
User entered 'Pfizer mRNA COVID-19 vaccine'	Leslie Iverson (b) (4) (b) (4)	27 Jan 2021 15:56:06

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Covid-19 prevention'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0.3'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mL (mL)'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'once (ONCE)'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Leslie Iverson (b) (4)	27 Jan 2021 15:56:06



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '06 Jan 2021'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '06 Jan 2021'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	Leslie Iverson (b) (4)	27 Jan 2021 15:56:06

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	27 Jan 2021 15:56:06

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	27 Jan 2021 15:56:06



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	27 Jan 2021 15:56:06

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
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: LORTAB [HYDROCODONE BITARTRATE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 09:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 09:00:42
Data point term sent to Coder	System	01 Feb 2021 17:13:37
User closed query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	01 Feb 2021 17:12:51
Query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'update' (Site from System).	Andryelle Toledo (b) (4)	01 Feb 2021 17:12:51
User entered 'LORTAB (Hydrocodone bitartrate and acetaminophen)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	01 Feb 2021 17:12:42
User opened query 'DM-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)	01 Feb 2021 15:33:29
Data point term sent to Coder	System	28 Jan 2021 20:54:04
User entered 'Lortab'	Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'LEFT CLAVICULAR FRACTURE'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '5-325'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '20 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 10:20:41**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:53:18



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Jan 2021 20:53:18

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Jan 2021 20:53:18

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	28 Jan 2021 20:53:18

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 18:44:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 18:44:31
Data point term sent to Coder User entered 'Cyclobenzaprine'	System Andryelle Toledo (b) (4) (b) (4)	02 Feb 2021 18:43:52 02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Left Clavicle fracture'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '5'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'mg (mg)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47



US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '23 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:43:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:43:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:43:47

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:43:47

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: ASPERCREME WITH LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 21:03:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:03:33
Data point term sent to Coder	System	02 Feb 2021 18:46:54
User entered 'Aspercreme with lidocaine 4%'	Andryelle Toledo (b) (4) (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Left Clavicle Fracture'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'I'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Other (OTHER)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 10:20:41**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'patch'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'as needed (PRN)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 10:20:41**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Topical (TOPICAL)'	Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 10:20:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '23 Dec 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59



US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:20:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:20:58
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Feb 2021 18:45:59

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 10:20:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:45:59

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:45:59

US3892033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 10:20:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered empty.	System	02 Feb 2021 18:45:59

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:20:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:59:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	05 Jan 2021 16:50:48
User entered 'No (N)'	(b) (4) chase Carnahan (b) (4)	01 Sep 2020 00:04:24



US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered '21 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 16:52:53

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'CT Brain'	Leslie Iverson (b) (4)	05 Jan 2021 16:52:53

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	05 Jan 2021 16:52:53

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 16:52:53

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 16:56:37

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'Shoulder X-ray Left'	Leslie Iverson (b) (4)	05 Jan 2021 16:56:37

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	05 Jan 2021 16:56:37

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 16:56:37



US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:21:44

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Per source this is noted as CT Spine/Cervical, should the be updated in EDC? Kindly update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:45:32
Query 'Per source this is noted as CT Spine/Cervical, should the be updated in EDC? Kindly update accordingly.' answered with 'CT Spine/Cervical Added' (Site from CRA).	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 16:50:48
User opened query 'Per source this is noted as CT Spine/Cervical, should the be updated in EDC? Kindly update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 22:04:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'CT Brain'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:21:44

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	05 Jan 2021 17:21:44

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:21:44

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	05 Jan 2021 17:22:44

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'X-RAY TIBIA/FIBULA (Right)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:23:28
User entered 'X-ray Tibia/Fibula'	Leslie Iverson (b) (4) (b) (4)	05 Jan 2021 17:22:44

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	19 Jan 2021 16:51:42
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	19 Jan 2021 16:51:02
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	05 Jan 2021 17:22:44
	(b) (4)	

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:12:51
User closed query 'Should X-ray Chest be added to EDC for 20DEC2020?' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 23:45:37
Query 'Should X-ray Chest be added to EDC for 20DEC2020?' answered with 'Chest x-ray added' (Site from CRA).	Leslie Iverson (b) (4)	19 Jan 2021 16:52:00
User entered empty; reason for change Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 16:51:42
DataPoint Un-verified.	Leslie Iverson (b) (4)	19 Jan 2021 16:51:02
User entered 'Chest x-ray added' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 16:51:02
User opened query 'Should X-ray Chest be added to EDC for 20DEC2020?' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 22:05:55
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 22:01:40
User entered empty.	Leslie Iverson (b) (4)	05 Jan 2021 17:22:44



US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:12:59
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:43:38

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:13:00
User entered 'CT SPINE CERVICAL WITHOUT CONTRAST' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 16:47:56
User entered 'CT Spine Cervical with contrast'	(b) (4) Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 16:43:38

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:02
User entered 'Diagnostic (DIAGNOSTIC)'	Leslie Iverson (b) (4)	19 Jan 2021 16:43:38

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:04
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 16:43:38

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:44:15

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:49
User entered 'X-RAY PELVIS' reason for change:	Andryelle Toledo (b) (4)	09 Apr 2021 15:57:58
Data Entry Error	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	09 Apr 2021 15:57:31
Signature has been broken.	(b) (4)	
	Andryelle Toledo (b) (4)	09 Apr 2021 15:57:31
User entered 'X-RAY PELVIS with contrast' reason	Andryelle Toledo (b) (4)	09 Apr 2021 15:57:31
for change: Data Entry Error	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered 'X-ray pelvis'	Leslie Iverson (b) (4)	19 Jan 2021 16:44:15
	(b) (4)	

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered 'Diagnostic (DIAGNOSTIC)'	Leslie Iverson (b) (4)	19 Jan 2021 16:44:15

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 16:44:15



US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered '20 Dec 2020'	Leslie Iverson (b) (4)	19 Jan 2021 16:50:29

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered 'Chest X-ray'	Leslie Iverson (b) (4)	19 Jan 2021 16:50:29

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	19 Jan 2021 16:50:29

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 16:50:29

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:20:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered '21 Dec 2020'	Leslie Iverson (b) (4)	27 Jan 2021 15:08:41

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:20:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered 'Debridement R leg hematoma'	Leslie Iverson (b) (4)	27 Jan 2021 15:08:41

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:20:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	27 Jan 2021 15:08:41

US3892033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:20:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:13:27
User entered empty.	Leslie Iverson (b) (4)	27 Jan 2021 15:08:41



US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:41

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '27 Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:41

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

US3892033

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 10 Jun 2021 10:20:41**

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)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered 'Subject received outside EUA vaccine (Pfizer mRNA LNP-S)'	Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:41

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:41

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:41

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

US3892033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:41

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Jan 2021 20:49:50

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:20:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
User entered '29/Dec/2020 11:42'	System	29 Dec 2020 16:42:03



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:20:41

**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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:20:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
User entered '30/Dec/2020 09:58'	System	30 Dec 2020 14:58:49

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:20:41

**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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:11:14
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 14:58:49

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38



**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 10:20:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:43:56
User entered '28/Jan/2021 14:11'	System	28 Jan 2021 14:11:23

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:20:41

**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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:24:22
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:43:56
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 14:11:23

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 10:20:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:05:23
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '24/Feb/2021 10:24'	(b) (4) System	24 Feb 2021 16:24:36

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:20:41

**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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:05:25
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 17:09:21
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:24:36

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 10:20:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:05:10
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '24/Feb/2021 11:32'	(b) (4) System	24 Feb 2021 17:32:54



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:20:41

**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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 16:09:19
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:05:12
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:32:54
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 17:20:35

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'USA-US209-2020-MRNA-1273-P301000002'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Yes (Y)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'No (N)'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Michael'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Adams'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '5251 S Green St'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'Murray'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered 'UT'	System	29 Dec 2020 16:41:38

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:20:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:41:56
User entered '84123'	System	29 Dec 2020 16:41:38

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:49:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:58:38
User entered 'US'	System	29 Dec 2020 16:42:03



US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
User entered '6'	System	24 Mar 2021 16:09:33
User entered '5'	System	24 Feb 2021 17:32:54
User entered '4'	System	24 Feb 2021 16:24:36
User entered '3'	System	28 Jan 2021 14:11:23
User entered '2'	System	30 Dec 2020 14:58:49
User entered '1'	System	29 Dec 2020 16:42:03

**US3892033**

**Folder: SAE USA-US209-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 10:20:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:37:06
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:42:28
User entered '24/Mar/2021 11:09'	(b) (4) System	24 Mar 2021 16:09:33

US3892033

Folder: SAE USA-US209-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:20:41

**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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:05:50
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:37:06
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:42:28
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 16:09:33