

US3462133 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:42:27

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US3462133

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

[Participant ID](#)

US3462133

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

US3462133

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input 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) 19 Feb 2021 19:49:37

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Date of Informed Consent (<i>dd MMM yyyy</i>)	12 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 checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:49:37

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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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	OCCASIONAL HEADACHES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462133

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	NECK PAIN
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	OCCASIONAL SEIZURES
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Condition	MORPHINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462133

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:31 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 07:31
Height (<i>xxx.x</i>)	172 cm
Weight (<i>xxx.x</i>)	47.7 kg
BMI (<i>xxx.x</i>)	16.12358 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 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: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 19:49:37

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Date of assessment (*dd MMM yyyy*) 12 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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 ☐

Specify

GROCERY STORE 2X WEEKLY -
RESTAURANT 2X WEEKLY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:49:37

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103309

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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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)	12 AUG 2020
Time of assessment (00:00-23:59)	07:31 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 07:31
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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)	12 AUG 2020
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:07
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 08:32 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 08:32

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) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 AUG 2020

Collection time (00:00-23:59)

08:04 (24 HR)

Collection date and time (derived)

12 AUG 2020 08:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:06	12 AUG 2020 08:06
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

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: 09 Jun 2021 17:42:27

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

98.5 °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

12 AUG 2020 09:06

PC Open Date & Time

12 AUG 2020 08:52

PC Close Date & Time

12 AUG 2020 11:22

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	12 AUG 2020 17:23
PC Open Date & Time	12 AUG 2020 12:17
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 17:22

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

97.6 °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

14 AUG 2020 18:07

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

15 AUG 2020 17:47

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 17:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

17 AUG 2020 17:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

97.7 °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

18 AUG 2020 17:10

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

12 AUG 2020 09:07

PC Open Date & Time

12 AUG 2020 08:52

PC Close Date & Time

12 AUG 2020 11:22

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

12 AUG 2020 17:24

PC Open Date & Time

12 AUG 2020 12:17

PC Close Date & Time

13 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

13 AUG 2020 17:23

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

14 AUG 2020 18:07

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

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

15 AUG 2020 17:48

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

16 AUG 2020 17:12

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

17 AUG 2020 17:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

18 AUG 2020 17:10

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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 ☐

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 09:08
PC Open Date & Time	12 AUG 2020 08:52
PC Close Date & Time	12 AUG 2020 11:22

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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 ☐

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 17:24
PC Open Date & Time	12 AUG 2020 12:17
PC Close Date & Time	13 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

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 ☒

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:24
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

56 of 1072

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:49
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:13
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 17:05
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 17:11
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3462133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3462133

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462133

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462133

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:49:37

Generated On: 09 Jun 2021 17:42:27

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3462133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:42:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

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Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:42:27

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:42:27

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:27

Date of updated informed consent (*dd MMM yyyy*)

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3462133

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:27

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3462133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:27

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3462133

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

AEID	USA-US093-2020-MRNA-1273-P30 1000001
Adverse event	GENERALIZED SEIZURES
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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 AUG 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 type="radio"/> Grade 4 <input checked="" 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)	23 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	26 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

61 YEAR OLD WOMAN WITH
PMH OF HYPERTENSION AND
ALSO PRIOR SEIZURE
DISORDER OCCURRING
OCT2019 AND MAR2020
POSSIBLE DUE TO ALCOHOL
WITHDRAWAL, QUALIFIED TO
SCREEN AND RANDOMIZE
MODERNA ON 12AUG2020. NO
ADVERSE REACTIONS TO
VACCINE PER PHONE CALL ON
19AUG2020. HOWEVER,
PATIENT DID HAVE
GENERALIZED SEIZURES (?
GRAND MAL) AT 09:00 ON
23AUG2020. PATIENT WAS
FOAMING AT THE MOUTH,
EYES ROLLED BACK IN HER
HEAD, AND SHE WAS STIFF.
SHE DID SHAKE AT THE END,
ESTIMATES EPISODE LASTED 8
MINUTES, SHE WAS CONFUSED
AFTER. SHE WAS BROUGHT TO
LOCAL ER BY PARAMEDICS
HAD A SECOND SEIZURE AT
10:30AM ON 23AUG2020.
PATIENT WAS ADMITTED TO
LOCAL HOSPITAL
23-28AUG2020. SHE WAS
STARTED ON
ANTICONVULSANT
LEVITIRACETAM 500 MG BID
AND HAD NO FURTHER
SEIZURES. WORKUP INCLUDED
A CT SCAN WITH AND

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

WITHOUT CONTRAST WHICH
REVEALED A NEW AREA OF
ENCEPHALOMALACIA WITHIN
THE RIGHT OCCIPITAL LOBE
SUGGESTIVE OF SUBACUTE TO
MORE REMOTE INFARCTION
BUT NEW WHEN COMPARED
TO 26FEB2020 STUDY.
INCIDENTAL 3-4 MM RIGHT
SUPERIOR HYPOPHYAL
ANEURYSM. MRI SHOWED A
SMALL AREA OF CHRONIC
APPEARING
ENCEPHALOMALACIA IN THE
RIGHT TEMPORAL OCCIPITAL
REGION. THIS CORRESPONDS
TO THE RECENT CT SCAN. AN
ECHOCARDIOGRAM
DEMONSTRATED REDUCED
EJECTION FRACTION (31%)
APICAL BALLOONING WITH
SEVERE LEFT VENTRICULAR
IMPAIRMENT. ALSO MARKED
ENLARGEMENT OF THE RIGHT
ATRIUM. NEGATIVE STUDY
FOR PFO. LABS SHOWED MILD
HYPOKALEMIA AND
HYPONATREMIA WHICH
IMPROVED WITH
REHYDRATION. THESE WERE
THOUGH RELATED TO
EXCESSIVE ALCOHOL INTAKE.
SHE WAS DISCHARGED TO
HOME RECOVERED ON
28AUG2020 ON KEPRA FOR

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

SEIZURE PROPHYLAXIS, ALSO
WITH ADJUSTMENTS IN HTN
MEDICATIONS, AND A NEW
STATIN ADDED. SAE OF
GENERALIZED SEIZURES IS
NOT RELATED TO STUDY MED.
OR STUDY PROCEDURES ON
12AUG2020, BUT IS LIKELY
RELATED TO HER PAST
MEDICAL HISTORY OF
IDIOPATHIC SEIZURES SINCE
OCT2019. PATIENT IS UNABLE
TO TRAVEL AND SO CANNOT
COMPLETE ANY OTHER VISITS.
PATIENT WITHDREW CONSENT
AND STOPPED ALL STUDY
RELATED PROCEDURES.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

AEID

Adverse event

RIGHT TEMPORAL CVA

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)

23 AUG 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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

AEID

Adverse event

HEART FAILURE

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)

23 AUG 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 22:55:17

Generated On: 09 Jun 2021 17:42:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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 type="radio"/> Unknown <input checked="" 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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 (3)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 00:44:54

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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 AUG 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 (5)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication LEVETIRACETAM

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED SEIZURES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication HEART FAILURE

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 (7)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 SEP 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 (8)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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 AUG 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 (9)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication DISULFIRAM

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL CESSATION

Dose per administration 250

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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

	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)	26 AUG 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 (11)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication NICOTINE PATCH

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 14

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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

Name of Medication NICOTINE GUM

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:42:27

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 AUG 2020	LABS	Adverse Event	
24 AUG 2020	CT ANGIOGRAM HEAD	Adverse Event	
25 AUG 2020	MRI BRAIN WITH AND WITHOUT CONTRAST	Adverse Event	
23 AUG 2020	CT HEAD WITHOUT CONTRAST	Adverse Event	
24 AUG 2020	CT ANGIOGRAM NECK	Adverse Event	
25 AUG 2020	ECHO 2D COMPLETE DOPPLER COLOR FLOW	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Apr 2021 21:10:53

Generated On: 09 Jun 2021 17:42:27

Date of dosing discontinuation (dd MMM yyyy)	12 AUG 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <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 type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input checked="" type="checkbox"/>
	Due to SARS-COV-2 <input type="checkbox"/>
	Other <input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	PATIENT WITHDREW CONSENT DUE TO UNSTABLE HEALTH.
---	--

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Apr 2021 21:10:53

Generated On: 09 Jun 2021 17:42:27

Date of study discontinuation/completion (dd MMM yyyy) 14 SEP 2020

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 type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify PATIENT WITHDREW CONSENT DUE TO UNSTABLE HEALTH.

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"/>

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US093-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US093-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/SEP/2020 14:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US093-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/OCT/2020 18:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US093-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/OCT/2020 13:53
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

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 19:49:36

Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US093-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 12:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3462133 (Prod: Crisor, LLC)

US3462133

Form: Participant Creation

Generated On: 09 Jun 2021 17:42:27

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'US3462133'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:39:53

US3462133

Form: Participant Creation

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08

US3462133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:36:49
User entered 'Yes (Y)'		12 Aug 2020 15:44:00

US3462133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:36:49
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:39:54

US3462133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:36:49
User entered 'Clinic (Clinic)'		12 Aug 2020 15:44:00

US3462133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'SCRN'	System	12 Aug 2020 15:44:00

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:39:55

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	19 Oct 2020 21:00:15
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 21:00:15
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	13 Aug 2020 16:29:10
User entered '62'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'YEARS'	System	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '61'	System	12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered 'Female (F)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered 'I'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:37:05
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:29:10

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered '12 Aug 2020'		12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Aug 2020'	System	12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2020'	System	12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered 'Amendment 2 (2)'		12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered 'Yes (Y)'		12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered empty.		12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered empty.		12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered 'No (N)'		12 Aug 2020 15:44:19

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:39:54

US3462133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'I'	System	12 Aug 2020 15:44:25

US3462133

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:22
User entered 'Yes (Y)'		12 Aug 2020 15:44:25

US3462133

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:42:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:37:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:12

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User closed query 'Per source, please consider adding "Morphine Allergy" since 2000. ' (Site from CRA).	(b) (4)	
Query 'Per source, please consider adding "Morphine Allergy" since 2000. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 21:35:25
DataPoint Verified.		18 Jan 2021 22:43:09
User opened query 'Per source, please consider adding "Morphine Allergy" since 2000. ' (Site from CRA).		18 Nov 2020 22:41:13
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 16:33:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 16:32:00
User entered 'SEASONAL ALLERGIC RHINITIS'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 1978'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 1978'	System	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '1978'	System	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:31:27

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:33:21
Data point term sent to Coder	System	13 Aug 2020 16:32:00
User entered 'PERENNIAL ALLERGIC RHINITIS'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 1978'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 1978'	System	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '1978'	System	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:31:43

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		11 Nov 2020 21:11:58
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).		19 Oct 2020 21:00:56
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		01 Oct 2020 08:24:44
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:33:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:33:22
Data point term sent to Coder	System	13 Aug 2020 16:32:00
User entered 'HYPERTENSION'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 2000'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2000'	System	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2000'	System	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:31:54

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
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)	29 Jan 2021 13:15:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:15:53
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:13
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)	13 Aug 2020 16:34:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 16:34:27
Data point term sent to Coder	System	13 Aug 2020 16:33:01
User entered 'OCCASIONAL HEADACHES'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 2000'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2000'	System	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2000'	System	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:32:11

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:34:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:34:29
Data point term sent to Coder	System	13 Aug 2020 16:33:01
User entered 'BACK PAIN'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 2000'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2000'	System	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2000'	System	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:32:23

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
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: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:34:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:34:25
Data point term sent to Coder	System	13 Aug 2020 16:33:02
User entered 'NECK PAIN'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 2000'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2000'	System	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2000'	System	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:32:33

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:35:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:35:20
Data point term sent to Coder	System	13 Aug 2020 16:34:03
User entered 'Degenerative disc disease'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'UN UNK 2006'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2006'	System	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2006'	System	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:33:03

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:04:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:04:36
Data point term sent to Coder	System	19 Oct 2020 21:03:02
User entered 'post-menopausal'	(b) (4), (b) (6)	19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'un UNK 2010'		19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'		19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)'		19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty.		19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'		19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2010'	System	19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2010'	System	19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	19 Oct 2020 21:02:11

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:50
User closed query 'Please clarify spelling of "SEIZUE". 'R' (Site from CRA).		22 Jan 2021 21:35:48
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:25:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:25:09
Data point term sent to Coder	System	18 Jan 2021 22:43:06
Query 'Please clarify spelling of "SEIZUE". 'R' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	18 Jan 2021 22:42:39
DataPoint Un-verified.		18 Jan 2021 22:42:23
Coding entries removed.		18 Jan 2021 22:42:23
User entered 'OCCASIONAL SEIZUres' reason for change: Data Entry Error		18 Jan 2021 22:42:23
DataPoint Verified.		18 Nov 2020 22:41:13
User opened query 'Please clarify spelling of "SEIZUE". 'R' (Site from CRA).		18 Nov 2020 22:39:54
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:12:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:12:31
Data point term sent to Coder	System	21 Oct 2020 20:40:59
User entered 'occasional SEIZUE' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:40:39
User entered 'seizue'		21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'un Oct 2019'		21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'		21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered 'Yes (Y)' reason for change: Data Entry Error		21 Oct 2020 20:40:39
User entered 'No (N)'		21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered empty; reason for change Data Entry Error		21 Oct 2020 20:40:39
User entered 'un Oct 2019'		21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:41:13
User entered '0'		21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Oct 2019'	System	21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2019'	System	21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	21 Oct 2020 20:40:39
User entered 'Oct 2019'	System	21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	21 Oct 2020 20:40:39
User entered '2019'	System	21 Oct 2020 20:40:16

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:38
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 22:46:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 22:46:11
Data point term sent to Coder	System	18 Jan 2021 22:45:06
User entered 'Morphine Allergy'	(b) (4), (b) (6)	18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:38
User entered 'un UNK 2000'		18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:38
User entered '0'		18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:38
User entered 'Yes (Y)'		18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:38
User entered empty.		18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:35:38
User entered '0'		18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'Jan 2000'	System	18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '2000'	System	18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	18 Jan 2021 22:44:21

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered '07:31'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '12 Aug 2020 07:31'	System	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered '172' cm	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58
DataPoint set to visible.	System	12 Aug 2020 15:44:25

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered '47.7' kg	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58
DataPoint set to visible.	System	12 Aug 2020 15:44:25

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
Amendment Manager: User entered '16.12358'	System	16 Sep 2020 23:53:18
User entered '16.1'	System	13 Aug 2020 16:33:58
DataPoint set to visible.	System	12 Aug 2020 15:44:25

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'kg/m2'	System	13 Aug 2020 16:33:58
DataPoint set to visible.	System	12 Aug 2020 15:44:25

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:18:06
User entered '97.7' F	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:18:06
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:18:06
User entered '76'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'bpm'	System	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:18:06
User entered '14'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'breaths/min'	System	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:18:06
User entered '140'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'mmHg'	System	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:18:06
User entered '62'	Danuel Hamlin (b) (4)	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'mmHg'	System	13 Aug 2020 16:33:58

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16

US3462133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16

US3462133

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:44
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:04

US3462133

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:42:44
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:04

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:44:03
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:44:03
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:44:03
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		11 Nov 2020 21:11:02
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated' (Site from DM).		19 Oct 2020 21:00:42
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		09 Oct 2020 03:36:30
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:44:03
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:44:03
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:44:03
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:36:21
User closed query 'Per source registration form, subject's last cycle was 2010. Please clarify. ' (Site from CRA).		22 Jan 2021 21:36:18
Query 'Per source registration form, subject's last cycle was 2010. Please clarify. ' answered with 'corrected' (Site from CRA).		18 Jan 2021 22:41:45
DataPoint Un-verified.		18 Jan 2021 22:41:38
User entered 'un UNK 2010' reason for change: Data Entry Error		18 Jan 2021 22:41:38
DataPoint Verified.		18 Nov 2020 22:44:03
User opened query 'Per source registration form, subject's last cycle was 2010. Please clarify. ' (Site from CRA).		18 Nov 2020 22:44:00
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:27

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:36:22
DataPoint Un-verified.		18 Jan 2021 22:41:38
User entered '0' reason for change: Data Entry Error		18 Jan 2021 22:41:38
DataPoint Verified.		18 Nov 2020 22:44:03
User entered '1'	Danuel Hamlin (b) (4)	13 Aug 2020 16:34:32

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

[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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

[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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered 'GROCERY STORE 2X WEEKLY - RESTAURANT 2X WEEKLY'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

[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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered '0'	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:45:16
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:35:12

US3462133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:20
User entered 'Yes (Y)'		12 Aug 2020 15:44:37

US3462133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:20
User entered '12 Aug 2020'		12 Aug 2020 15:44:37

US3462133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:20
User entered 'Clinic (Clinic)'		12 Aug 2020 15:44:37

US3462133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'VISIT1'	System	12 Aug 2020 15:44:37

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:59:31

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:50:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:50:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 14:59:31
User entered '103309' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:59:31

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 14:59:31

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered 'No (N)'		12 Aug 2020 15:45:02

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered 'No (N)'		12 Aug 2020 15:45:02

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered 'No (N)'		12 Aug 2020 15:45:02

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered 'No (N)'		12 Aug 2020 15:45:02

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered 'No (N)'		12 Aug 2020 15:45:02

US3462133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:46:40
User entered 'No (N)'		09 Oct 2020 21:07:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:29
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:44:29

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered '172' cm	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered '47.7' kg	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered '172' cm	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered '47.7' kg	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '07:31'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '12 Aug 2020 07:31'	System	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '97.7' F	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '76'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'bpm'	System	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '14'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'breaths/min'	System	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '140'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'mmHg'	System	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '62'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'mmHg'	System	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered '172' cm	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered '47.7' kg	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:02

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		18 Aug 2020 06:15:10
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 16:36:43
User entered '09:07'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '12 Aug 2020 09:07'	System	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '98.5' F	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Oct 2020 18:17:07
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '76'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'bpm'	System	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '14'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'breaths/min'	System	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '140'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'mmHg'	System	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:48
User entered '84'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'mmHg'	System	13 Aug 2020 16:36:43

US3462133

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:53
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:51

US3462133

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:47:53
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:36:51

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:21
User entered 'Yes (Y)'		12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:21
User entered empty.		12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:21
User entered empty.		12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:21
User entered '12 Aug 2020'		12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:21
User entered '08:32'		12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '12 Aug 2020 08:32'	System	12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:21
User entered 'Left Arm (LEFT ARM)'		12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
DataPoint Verified.		18 Nov 2020 22:48:21
User entered 'ONCE'	System	12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 15:45:33

US3462133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:37
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:06

US3462133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:37
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:06

US3462133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:37
User entered '08:04'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:06

US3462133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '12 Aug 2020 08:04'	System	13 Aug 2020 16:37:06

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:42:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:49
User entered '12 Aug 2020'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:49
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:49
User entered '08:06'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered '12 Aug 2020 08:06'	System	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:49
User entered 'No (N)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:48:49
User entered empty.	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered empty.	System	13 Aug 2020 16:37:16

US3462133

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:55
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	13 Aug 2020 16:37:20

US3462133

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:16
User entered 'I'	System	13 Aug 2020 16:37:20

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:05:58', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'e6227655-fd8f-40a1-9e35-3d2529802140'	System	12 Aug 2020 16:06:56
User entered 'Yes (Y)'	System	12 Aug 2020 16:06:56

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:06:21', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'e6227655-fd8f-40a1-9e35-3d2529802140'	System	12 Aug 2020 16:06:56
User entered '98.5'	System	12 Aug 2020 16:06:56

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:06:44', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'e6227655-fd8f-40a1-9e35-3d2529802140'	System	12 Aug 2020 16:06:56
User entered 'No (N)'	System	12 Aug 2020 16:06:56

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:06:52', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'e6227655-fd8f-40a1-9e35-3d2529802140'	System	12 Aug 2020 16:06:56
User entered '12 Aug 2020 09:06'	System	12 Aug 2020 16:06:56

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 08:52'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 11:22'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:22:19', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '2eed9de2-ed56-4fef-af3a-fe35077adfbaf'	System	13 Aug 2020 00:23:13
User entered 'Yes (Y)'	System	13 Aug 2020 00:23:13

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:22:45', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '2eed9de2-ed56-4fef-af3a-fe35077adfbaf'	System	13 Aug 2020 00:23:13
User entered '97.6'	System	13 Aug 2020 00:23:13

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:22:54', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '2eed9de2-ed56-4fef-af3a-fe35077adfbaf'	System	13 Aug 2020 00:23:13
User entered 'No (N)'	System	13 Aug 2020 00:23:13

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:23:11', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '2eed9de2-ed56-4fef-af3a-fe35077adfbba'	System	13 Aug 2020 00:23:13
User entered '12 Aug 2020 17:23'	System	13 Aug 2020 00:23:13

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 12:17'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 2'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:21:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'd36c0236-679b-4024-a24c-d9fbdb578d1e' User entered 'Yes (Y)'	System	14 Aug 2020 00:22:42
	System	14 Aug 2020 00:22:42

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:22:19', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'd36c0236-679b-4024-a24c-d9fbdb578d1e' User entered '96.3'	System	14 Aug 2020 00:22:42
	System	14 Aug 2020 00:22:42

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:22:25', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'd36c0236-679b-4024-a24c-d9fbd578d1e'	System	14 Aug 2020 00:22:42
User entered 'No (N)'	System	14 Aug 2020 00:22:42

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:22:40', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'd36c0236-679b-4024-a24c-d9fbdb578d1e'	System	14 Aug 2020 00:22:42
User entered '13 Aug 2020 17:22'	System	14 Aug 2020 00:22:42

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 3'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:06:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5851fae7-522a-4267-ae92-c878e7351cd5'	System	15 Aug 2020 01:07:09
User entered 'Yes (Y)'	System	15 Aug 2020 01:07:09

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:06:53', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5851fae7-522a-4267-ae92-c878e7351cd5' User entered '97.6'	System	15 Aug 2020 01:07:09
	System	15 Aug 2020 01:07:09

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:06:58', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5851fae7-522a-4267-ae92-c878e7351cd5'	System	15 Aug 2020 01:07:09
User entered 'No (N)'	System	15 Aug 2020 01:07:09

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:07', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5851fae7-522a-4267-ae92-c878e7351cd5'	System	15 Aug 2020 01:07:09
User entered '14 Aug 2020 18:07'	System	15 Aug 2020 01:07:09

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 4'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:47:12', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '67886e4d-ff67-40ae-92a5-26663d0c17aa' User entered 'Yes (Y)'	System	16 Aug 2020 00:47:37
	System	16 Aug 2020 00:47:37

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:47:24', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '67886e4d-ff67-40ae-92a5-26663d0c17aa' User entered '97.4'	System	16 Aug 2020 00:47:37
	System	16 Aug 2020 00:47:37

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:47:30', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '67886e4d-ff67-40ae-92a5-26663d0c17aa'	System	16 Aug 2020 00:47:37
User entered 'No (N)'	System	16 Aug 2020 00:47:37

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:47:34', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '67886e4d-ff67-40ae-92a5-26663d0c17aa' User entered '15 Aug 2020 17:47'	System	16 Aug 2020 00:47:37
	System	16 Aug 2020 00:47:37

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 5'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:05', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '80c9dab2-9178-4f85-aab0-4c62b2bc50a7'	System	17 Aug 2020 00:12:26
User entered 'Yes (Y)'	System	17 Aug 2020 00:12:26

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:15', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '80c9dab2-9178-4f85-aab0-4c62b2bc50a7' User entered '97.8'	System	17 Aug 2020 00:12:26
	System	17 Aug 2020 00:12:26

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:20', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '80c9dab2-9178-4f85-aab0-4c62b2bc50a7'	System	17 Aug 2020 00:12:26
User entered 'No (N)'	System	17 Aug 2020 00:12:26

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:23', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '80c9dab2-9178-4f85-aab0-4c62b2bc50a7'	System	17 Aug 2020 00:12:26
User entered '16 Aug 2020 17:12'	System	17 Aug 2020 00:12:26

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 6'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:04:15', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c5be340c-7fed-4fdd-a13b-a2b79d0291b6'	System	18 Aug 2020 00:04:50
User entered 'Yes (Y)'	System	18 Aug 2020 00:04:50

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:04:39', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c5be340c-7fed-4fdd-a13b-a2b79d0291b6' User entered '97.2'	System	18 Aug 2020 00:04:50
	System	18 Aug 2020 00:04:50

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:04:44', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c5be340c-7fed-4fdd-a13b-a2b79d0291b6'	System	18 Aug 2020 00:04:50
User entered 'No (N)'	System	18 Aug 2020 00:04:50

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:04:47', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c5be340c-7fed-4fdd-a13b-a2b79d0291b6'	System	18 Aug 2020 00:04:50
User entered '17 Aug 2020 17:04'	System	18 Aug 2020 00:04:50

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 7'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:09:44', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'abd84490-328b-46bf-8293-ee9e693f32c4'	System	19 Aug 2020 00:10:14
User entered 'Yes (Y)'	System	19 Aug 2020 00:10:14

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:04', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'abd84490-328b-46bf-8293-ee9e693f32c4'	System	19 Aug 2020 00:10:14
User entered '97.7'	System	19 Aug 2020 00:10:14

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:09', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'abd84490-328b-46bf-8293-ee9e693f32c4'	System	19 Aug 2020 00:10:14
User entered 'No (N)'	System	19 Aug 2020 00:10:14

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:12', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'abd84490-328b-46bf-8293-ee9e693f32c4'	System	19 Aug 2020 00:10:14
User entered '18 Aug 2020 17:10'	System	19 Aug 2020 00:10:14

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:07:10', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '99c42c2c-25a4-45bd-85d9-0c3ab76258a5' User entered 'None (1)'	System	12 Aug 2020 16:07:45
	System	12 Aug 2020 16:07:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:07:18', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '99c42c2c-25a4-45bd-85d9-0c3ab76258a5' User entered 'No (N)'	System	12 Aug 2020 16:07:45
	System	12 Aug 2020 16:07:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:07:24', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '99c42c2c-25a4-45bd-85d9-0c3ab76258a5' User entered 'No (N)'	System	12 Aug 2020 16:07:45
	System	12 Aug 2020 16:07:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:07:37', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '99c42c2c-25a4-45bd-85d9-0c3ab76258a5' User entered 'None (1)'	System	12 Aug 2020 16:07:45
	System	12 Aug 2020 16:07:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:07:44', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '99c42c2c-25a4-45bd-85d9-0c3ab76258a5' User entered '12 Aug 2020 09:07'	System	12 Aug 2020 16:07:45
	System	12 Aug 2020 16:07:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 08:52'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 11:22'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:23:21', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '46a32c92-e8bb-40ce-a67b-2635ec579a23'	System	13 Aug 2020 00:24:10
User entered 'None (1)'	System	13 Aug 2020 00:24:10

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:23:27', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '46a32c92-e8bb-40ce-a67b-2635ec579a23'	System	13 Aug 2020 00:24:10
User entered 'No (N)'	System	13 Aug 2020 00:24:10

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:23:35', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '46a32c92-e8bb-40ce-a67b-2635ec579a23'	System	13 Aug 2020 00:24:10
User entered 'No (N)'	System	13 Aug 2020 00:24:10

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:00', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '46a32c92-e8bb-40ce-a67b-2635ec579a23' User entered 'None (1)'	System	13 Aug 2020 00:24:10
	System	13 Aug 2020 00:24:10

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:07', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '46a32c92-e8bb-40ce-a67b-2635ec579a23'	System	13 Aug 2020 00:24:10
User entered '12 Aug 2020 17:24'	System	13 Aug 2020 00:24:10

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 12:17'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 2'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:22:56', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'ee7dd3ce-987a-496e-988f-9de6a7d3c064'	System	14 Aug 2020 00:23:39
User entered 'None (1)'	System	14 Aug 2020 00:23:39

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:03', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'ee7dd3ce-987a-496e-988f-9de6a7d3c064'	System	14 Aug 2020 00:23:39
User entered 'No (N)'	System	14 Aug 2020 00:23:39

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:10', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'ee7dd3ce-987a-496e-988f-9de6a7d3c064'	System	14 Aug 2020 00:23:39
User entered 'No (N)'	System	14 Aug 2020 00:23:39

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:17', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'ee7dd3ce-987a-496e-988f-9de6a7d3c064'	System	14 Aug 2020 00:23:39
User entered 'None (1)'	System	14 Aug 2020 00:23:39

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:35', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'ee7dd3ce-987a-496e-988f-9de6a7d3c064'	System	14 Aug 2020 00:23:39
User entered '13 Aug 2020 17:23'	System	14 Aug 2020 00:23:39

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 3'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:16', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '197b77de-39ba-4efd-ae3f-d782626e004f' User entered 'None (1)'	System	15 Aug 2020 01:07:51
	System	15 Aug 2020 01:07:51

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:27', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '197b77de-39ba-4efd-ae3f-d782626e004f'	System	15 Aug 2020 01:07:51
User entered 'No (N)'	System	15 Aug 2020 01:07:51

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:31', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '197b77de-39ba-4efd-ae3f-d782626e004f'	System	15 Aug 2020 01:07:51
User entered 'No (N)'	System	15 Aug 2020 01:07:51

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '197b77de-39ba-4efd-ae3f-d782626e004f' User entered 'None (1)'	System	15 Aug 2020 01:07:51
	System	15 Aug 2020 01:07:51

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:47', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '197b77de-39ba-4efd-ae3f-d782626e004f'	System	15 Aug 2020 01:07:51
User entered '14 Aug 2020 18:07'	System	15 Aug 2020 01:07:51

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 4'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:47:57', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c9a0879c-fd8a-42a2-993b-4772b9edeb87' User entered 'None (1)'	System	16 Aug 2020 00:48:50
	System	16 Aug 2020 00:48:50

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:48:01', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c9a0879c-fd8a-42a2-993b-4772b9edeb87'	System	16 Aug 2020 00:48:50
User entered 'No (N)'	System	16 Aug 2020 00:48:50

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:48:17', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c9a0879c-fd8a-42a2-993b-4772b9edeb87' User entered 'No (N)'	System	16 Aug 2020 00:48:50
	System	16 Aug 2020 00:48:50

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:48:26', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c9a0879c-fd8a-42a2-993b-4772b9edeb87' User entered 'None (1)'	System	16 Aug 2020 00:48:50
	System	16 Aug 2020 00:48:50

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:48:48', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c9a0879c-fd8a-42a2-993b-4772b9edeb87'	System	16 Aug 2020 00:48:50
User entered '15 Aug 2020 17:48'	System	16 Aug 2020 00:48:50

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 5'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:29', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8d01ec0c-1463-45c1-a903-709ad04d01e7' User entered 'None (1)'	System	17 Aug 2020 00:12:45
	System	17 Aug 2020 00:12:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:32', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8d01ec0c-1463-45c1-a903-709ad04d01e7'	System	17 Aug 2020 00:12:45
User entered 'No (N)'	System	17 Aug 2020 00:12:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8d01ec0c-1463-45c1-a903-709ad04d01e7' User entered 'No (N)'	System	17 Aug 2020 00:12:45
	System	17 Aug 2020 00:12:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:40', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8d01ec0c-1463-45c1-a903-709ad04d01e7' User entered 'None (1)'	System	17 Aug 2020 00:12:45
	System	17 Aug 2020 00:12:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:43', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8d01ec0c-1463-45c1-a903-709ad04d01e7'	System	17 Aug 2020 00:12:45
User entered '16 Aug 2020 17:12'	System	17 Aug 2020 00:12:45

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 6'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:04:54', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '59e30a1a-32db-4dd7-ad80-696d04d05471' User entered 'None (1)'	System	18 Aug 2020 00:05:23
	System	18 Aug 2020 00:05:23

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:00', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '59e30a1a-32db-4dd7-ad80-696d04d05471'	System	18 Aug 2020 00:05:23
User entered 'No (N)'	System	18 Aug 2020 00:05:23

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:06', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '59e30a1a-32db-4dd7-ad80-696d04d05471'	System	18 Aug 2020 00:05:23
User entered 'No (N)'	System	18 Aug 2020 00:05:23

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:11', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '59e30a1a-32db-4dd7-ad80-696d04d05471' User entered 'None (1)'	System	18 Aug 2020 00:05:23
	System	18 Aug 2020 00:05:23

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:18', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '59e30a1a-32db-4dd7-ad80-696d04d05471'	System	18 Aug 2020 00:05:23
User entered '17 Aug 2020 17:05'	System	18 Aug 2020 00:05:23

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 7'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:17', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '73a1d850-ca07-44ef-b20c-f5c6d747b68f' User entered 'None (1)'	System	19 Aug 2020 00:10:33
	System	19 Aug 2020 00:10:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:20', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '73a1d850-ca07-44ef-b20c-f5c6d747b68f'	System	19 Aug 2020 00:10:33
User entered 'No (N)'	System	19 Aug 2020 00:10:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:24', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '73a1d850-ca07-44ef-b20c-f5c6d747b68f'	System	19 Aug 2020 00:10:33
User entered 'No (N)'	System	19 Aug 2020 00:10:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:27', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '73a1d850-ca07-44ef-b20c-f5c6d747b68f' User entered 'None (1)'	System	19 Aug 2020 00:10:33
	System	19 Aug 2020 00:10:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:30', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '73a1d850-ca07-44ef-b20c-f5c6d747b68f'	System	19 Aug 2020 00:10:33
User entered '18 Aug 2020 17:10'	System	19 Aug 2020 00:10:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:16', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf'	System	12 Aug 2020 16:08:57
User entered 'None (0)'	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:24', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf'	System	12 Aug 2020 16:08:57
User entered 'None (0)'	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:28', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf' User entered 'None (0)'	System	12 Aug 2020 16:08:57
	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:33', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf' User entered 'None (0)'	System	12 Aug 2020 16:08:57
	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf'	System	12 Aug 2020 16:08:57
User entered 'None (0)'	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:42', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf' User entered 'None (0)'	System	12 Aug 2020 16:08:57
	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:50', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf'	System	12 Aug 2020 16:08:57
User entered 'No (N)'	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T09:08:55', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'a14d24fb-bbc9-413d-9923-fc8c335d47cf' User entered '12 Aug 2020 09:08'	System	12 Aug 2020 16:08:57
	System	12 Aug 2020 16:08:57

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 08:52'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 11:22'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:16', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'None (0)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:23', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'None (0)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:27', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'None (0)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:31', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'None (0)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'None (0)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:42', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'None (0)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:50', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered 'No (N)'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-12T17:24:57', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '3f61845f-13c5-455a-ab48-186fc76bfc56'	System	13 Aug 2020 00:25:01
User entered '12 Aug 2020 17:24'	System	13 Aug 2020 00:25:01

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '12 Aug 2020 12:17'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 2'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:42', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c'	System	14 Aug 2020 00:24:17
User entered 'None (0)'	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:46', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c'	System	14 Aug 2020 00:24:17
User entered 'None (0)'	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:51', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c' User entered 'None (0)'	System	14 Aug 2020 00:24:17
	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:55', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c' User entered 'None (0)'	System	14 Aug 2020 00:24:17
	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:23:59', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c'	System	14 Aug 2020 00:24:17
User entered 'None (0)'	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:24:01', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c' User entered 'None (0)'	System	14 Aug 2020 00:24:17
	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:24:07', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c'	System	14 Aug 2020 00:24:17
User entered 'No (N)'	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-13T17:24:15', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '476b11df-fe4d-47c2-8b9a-bde0c64af77c'	System	14 Aug 2020 00:24:17
User entered '13 Aug 2020 17:24'	System	14 Aug 2020 00:24:17

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 3'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:07:57', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c'	System	15 Aug 2020 01:08:47
User entered 'None (0)'	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:00', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c'	System	15 Aug 2020 01:08:47
User entered 'None (0)'	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:04', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c' User entered 'None (0)'	System	15 Aug 2020 01:08:47
	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:11', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c' User entered 'None (0)'	System	15 Aug 2020 01:08:47
	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:17', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c' User entered 'None (0)'	System	15 Aug 2020 01:08:47
	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:21', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c' User entered 'None (0)'	System	15 Aug 2020 01:08:47
	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:26', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c'	System	15 Aug 2020 01:08:47
User entered 'No (N)'	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-14T18:08:31', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'c47e9a58-5fae-46f7-91b8-e9bb3263369c'	System	15 Aug 2020 01:08:47
User entered '14 Aug 2020 18:08'	System	15 Aug 2020 01:08:47

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 4'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:48:55', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fcbc748af' User entered 'None (0)'	System	16 Aug 2020 00:49:40
	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:48:59', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fcbc748af' User entered 'None (0)'	System	16 Aug 2020 00:49:40
	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:49:08', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fc748af'	System	16 Aug 2020 00:49:40
User entered 'None (0)'	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:49:21', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fc748af'	System	16 Aug 2020 00:49:40
User entered 'None (0)'	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:49:25', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fcbc748af' User entered 'None (0)'	System	16 Aug 2020 00:49:40
	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:49:28', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fcbc748af' User entered 'None (0)'	System	16 Aug 2020 00:49:40
	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:49:33', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fcbc748af'	System	16 Aug 2020 00:49:40
User entered 'No (N)'	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-15T17:49:37', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '7b7e8777-357e-410c-b4f4-4f0fc748af'	System	16 Aug 2020 00:49:40
User entered '15 Aug 2020 17:49'	System	16 Aug 2020 00:49:40

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 5'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:47', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered 'None (0)'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:50', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered 'None (0)'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:53', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered 'None (0)'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:12:57', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered 'None (0)'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:13:00', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered 'None (0)'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:13:03', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered 'None (0)'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:13:06', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a'	System	17 Aug 2020 00:13:11
User entered 'No (N)'	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-16T17:13:09', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: 'b77fc21c-d927-4595-a642-5093a2c9892a' User entered '16 Aug 2020 17:13'	System	17 Aug 2020 00:13:11
	System	17 Aug 2020 00:13:11

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 6'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:26', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'None (0)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:30', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'None (0)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:34', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'None (0)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:37', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'None (0)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:40', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'None (0)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:44', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'None (0)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:48', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered 'No (N)'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-17T17:05:53', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '5ee3b443-3456-4a85-9ea6-15978daa40f8'	System	18 Aug 2020 00:05:59
User entered '17 Aug 2020 17:05'	System	18 Aug 2020 00:05:59

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
Data entry locked.	System	12 Aug 2020 15:45:33
User entered 'Day 7'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:36', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered 'None (0)'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:40', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered 'None (0)'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:50', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered 'None (0)'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:54', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9' User entered 'None (0)'	System	19 Aug 2020 00:11:21
	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:10:58', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered 'None (0)'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:11:02', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered 'None (0)'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:11:14', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered 'No (N)'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA6AAED7-BD1B-48ED-AB9B-8D1211A09745)', Time: '2020-08-18T17:11:17', User OID: 'PatientReportedOutcome (US3462133)', ODM File OID: '8b9bb6c9-bb6d-4f6a-ba4e-0f03ec6d22f9'	System	19 Aug 2020 00:11:21
User entered '18 Aug 2020 17:11'	System	19 Aug 2020 00:11:21

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 15:45:33

US3462133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:26:33
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 15:45:33

US3462133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:14
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:04:40

US3462133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:14
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:04:40

US3462133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:14
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:04:40

US3462133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:14
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:04:40

US3462133

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:13:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:04:48

US3462133

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered 'I'	System	19 Oct 2020 21:04:48

US3462133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:17:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:05:17

US3462133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:17:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:45:01
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'		19 Oct 2020 21:05:39
answered with 'date is correct' (Site from System).		
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Oct 2020 21:05:17
User entered '31 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 21:05:17

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Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:17:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:05:17

US3462133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:17:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:05:17

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Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:13:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:05:45

US3462133

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered 'I'	System	19 Oct 2020 21:05:45

US3462133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:11:17
User entered 'Yes (Y)'		19 Oct 2020 21:06:00

US3462133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:11:17
User entered '03 Sep 2020'		19 Oct 2020 21:06:00

US3462133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:11:17
User entered 'Contact Made (CONTACT MADE)'		19 Oct 2020 21:06:00

US3462133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:11:17
User entered empty.		19 Oct 2020 21:06:00

US3462133

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:11:23
User entered 'No (N)'		19 Oct 2020 21:06:06

US3462133

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	19 Oct 2020 21:06:06

US3462133

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:42:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:10:35
User entered 'Yes (Y)'		31 Aug 2020 20:44:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
Reviewed for Safety.		01 Sep 2020 18:22:01
User entered 'USA-US093-2020-mRNA-1273-P301000001'	System	01 Sep 2020 18:21:51
User entered 'New'	(b) (4), (b) (6)	01 Sep 2020 18:21:51

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Intermittent Seizures. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 16:30:29
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Intermittent Seizures. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'not worsening just repeating' (Site from DM).		26 Jan 2021 17:53:21
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Intermittent Seizures. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).		29 Nov 2020 11:46:45
DataPoint Verified.		17 Nov 2020 20:08:43
User closed query 'PV Query: Please consider updating the event term to the final diagnosis (i.e. Type of seizure), when information becomes available. ' (Site from Safety).		22 Oct 2020 18:02:42
User coded data point as SOC: Nervous system disorders, HLT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 23:44:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 23:44:49
Data point term sent to Coder	System	21 Oct 2020 20:25:21
Query 'PV Query: Please consider updating the event term to the final diagnosis (i.e. Type of seizure), when information becomes available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:24:55
Coding entries removed.		21 Oct 2020 20:24:49
User entered 'generalized SEIZURES' reason for change: Data Entry Error		21 Oct 2020 20:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the final diagnosis (i.e. Type of seizure), when information becomes available. ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 03:49:42
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:31:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:31:39
Data point term sent to Coder	System	31 Aug 2020 21:17:52
User entered 'recurrent seizures'	(b) (4), (b) (6)	31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Yes (Y)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '23 Aug 2020'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User closed query 'Per CDM: Per previous query, start time is not required unless the AE starts within 24 hours of dosing. If start date is correct, please remove time.' (Site from DM).		26 Oct 2020 15:08:06
Query 'Per CDM: Per previous query, start time is not required unless the AE starts within 24 hours of dosing. If start date is correct, please remove time.' answered with 'updated' (Site from DM).		21 Oct 2020 19:59:43
User entered empty; reason for change Data Entry Error		21 Oct 2020 19:59:28
User opened query 'Per CDM: Per previous query, start time is not required unless the AE starts within 24 hours of dosing. If start date is correct, please remove time.' (Site from DM).		02 Sep 2020 08:32:16
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		02 Sep 2020 08:24:35
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'time is correct' (Site from System).		31 Aug 2020 21:40:21
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 21:17:49
User entered '09:00'	(b) (4), (b) (6)	31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	21 Oct 2020 19:59:28
User entered '23 Aug 2020 09:00'	System	31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
User closed query 'Per DM CLR: Please review the dates of this AE as it is no expected that an episode of seizure would have a duration of more than a single date. Please reconcile and update the dates as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review the dates of this AE as it is no expected that an episode of seizure would have a duration of more than a single date. Please reconcile and update the dates as appropriate. Otherwise, clarify.' answered with 'per PI dates are correct' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:31:01
User opened query 'Per DM CLR: Please review the dates of this AE as it is no expected that an episode of seizure would have a duration of more than a single date. Please reconcile and update the dates as appropriate. Otherwise, clarify.' (Site from DM).		26 Jan 2021 17:53:17
DataPoint Verified.		29 Nov 2020 11:46:58
User entered '26 Aug 2020' reason for change: Data Entry Error		17 Nov 2020 20:08:43
User entered '28 Aug 2020'		27 Oct 2020 19:44:16
		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User closed query 'Per CDM: Per previous query, End time is not required unless the AE starts within 24 hours of dosing. If start date is correct, please remove time.' (Site from DM).		26 Oct 2020 15:08:09
Query 'Per CDM: Per previous query, End time is not required unless the AE starts within 24 hours of dosing. If start date is correct, please remove time.' answered with 'updated' (Site from DM).		21 Oct 2020 19:59:38
User entered empty; reason for change Data Entry Error		21 Oct 2020 19:59:28
User opened query 'Per CDM: Per previous query, End time is not required unless the AE starts within 24 hours of dosing. If start date is correct, please remove time.' (Site from DM).		02 Sep 2020 08:33:14
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).		02 Sep 2020 08:32:38
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'time is correct' (Site from System).		31 Aug 2020 21:40:23
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	31 Aug 2020 21:17:49
User entered '09:00'	(b) (4), (b) (6)	31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	21 Oct 2020 19:59:28
User entered '28 Aug 2020 09:00'	System	31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
Query 'PV Query: The event intensity is "Grade 4" for this event. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criteria or please reassess the event intensity grade.' canceled (Site from Safety).		02 Oct 2020 20:58:34
User opened query 'PV Query: The event intensity is "Grade 4" for this event. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criteria or please reassess the event intensity grade.' (Site from Safety).		10 Sep 2020 03:50:40
Query 'Per ETRTR:Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating even to grade 3' canceled (Site from CRA).		06 Sep 2020 18:48:23
User opened query 'Per ETRTR:Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating even to grade 3' (Site from CRA).		02 Sep 2020 15:16:24
User entered 'Grade 4 (Grade 4)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Yes (Y)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'l'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '23 Aug 2020'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '26 Aug 2020' reason for change: Data Entry Error		27 Oct 2020 19:43:56
User entered '28 Aug 2020'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Not Related (NOT RELATED)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Not Related (NOT RELATED)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User closed query 'Per CDM re-query: Per previous response 'Patient withdrew consent due to health, not specific SAE.', however 'Action taken with Investigational Product' is still recorded as Investigational Product Withdrawn. If IP was not withdrawn due to this Adverse Event, please update the response as appropriate.' (Site from DM).		13 Nov 2020 14:40:19
Query 'Per CDM re-query: Per previous response 'Patient withdrew consent due to health, not specific SAE.', however 'Action taken with Investigational Product' is still recorded as Investigational Product Withdrawn. If IP was not withdrawn due to this Adverse Event, please update the response as appropriate.' answered with 'updated' (Site from DM)		05 Nov 2020 17:05:12
User entered 'None (NONE)' reason for change: Data Entry Error		05 Nov 2020 17:05:03
User opened query 'Per CDM re-query: Per previous response 'Patient withdrew consent due to health, not specific SAE.', however 'Action taken with Investigational Product' is still recorded as Investigational Product Withdrawn. If IP was not withdrawn due to this Adverse Event, please update the response as appropriate.' (Site from DM).		29 Oct 2020 14:49:37
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		29 Oct 2020 14:46:56
User closed query 'PV Query: Please confirm if the subject remains in the trial, when information becomes available during follow-up visit. Please assess action taken with study drug as applicable.' (Site from Safety).		22 Oct 2020 18:02:55

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Patient withdrew consent due to health, not specific SAE.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 20:25:39
Query 'PV Query: Please confirm if the subject remains in the trial, when information becomes available during follow-up visit. Please assess action taken with study drug as applicable. ' answered with 'updated' (Site from Safety).		21 Oct 2020 20:25:03
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Oct 2020 20:24:49
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:24:49
User opened query 'PV Query: Please confirm if the subject remains in the trial, when information becomes available during follow-up visit. Please assess action taken with study drug as applicable. ' (Site from Safety).		10 Sep 2020 03:49:10
Query 'Per ETRTR: Please update field upon PI decision on Day 28 09Sep20, thanks.' canceled (Site from CRA).		06 Sep 2020 18:48:26
User opened query 'Per ETRTR: Please update field upon PI decision on Day 28 09Sep20, thanks.' (Site from CRA).		02 Sep 2020 15:17:16
User entered 'None (NONE)'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'l'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		29 Oct 2020 14:51:32
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).		21 Oct 2020 20:36:23
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		02 Oct 2020 02:34:58
User entered '1'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.		19 Apr 2021 15:09:52
(Revised on 27 Jan 2021, AMR) PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety). User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:11:54
(Revised on 27 Jan 2021, AMR) PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'unable to obtain' (Site from Safety). User closed query 'PV Query: Please consider adding alcohol withdrawal as SAE. If it does not meet the criteria for reporting, please state so in your answer.' (Site from Safety). Query 'PV Query: Please consider adding alcohol withdrawal as SAE. If it does not meet the criteria for reporting, please state so in your answer.' answered with 'Not enough data to report SAE as alcohol withdraw ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:21:57 16 Feb 2021 18:49:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. (Revised on 27 Jan 2021, AMR) PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 21:38:06
User opened query 'PV Query: Please consider adding alcohol withdrawal as SAE. If it does not meet the criteria for reporting, please state so in your answer.' (Site from Safety).		27 Jan 2021 21:38:01
User closed query 'PV query: Please consider adding alcohol withdrawal as SAE. ' (Site from Safety).		27 Jan 2021 20:50:54
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).		27 Jan 2021 20:50:50
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'na' (Site from Safety).		26 Jan 2021 17:53:37
Query 'PV query: Please consider adding alcohol withdrawal as SAE. ' answered with 'na' (Site from Safety).		26 Jan 2021 17:53:31
User closed query 'PV Query: It was reported that the subject's hypertension medications were adjusted. Please provide blood pressure readings and clarify if medication was increased or decreased.' (Site from Safety).		18 Nov 2020 22:08:06
DataPoint Verified.		17 Nov 2020 20:08:43
Query 'PV Query: It was reported that the subject's hypertension medications were adjusted. Please provide blood pressure readings and clarify if medication was increased or decreased.' answered with 'This is already documented on Conmed page.' (Site from Safety).		17 Nov 2020 17:39:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please consider adding alcohol withdrawal as SAE. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:58:26
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).		13 Nov 2020 18:57:07
User opened query 'PV Query: It was reported that the subject's hypertension medications were adjusted. Please provide blood pressure readings and clarify if medication was increased or decreased.' (Site from Safety).		13 Nov 2020 18:56:29
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).		06 Nov 2020 17:01:57
User closed query 'PV Query: Please provide specific treatment drug names of medications that were adjusted for hypertension and the new "statin" medication. Please add medications to CM eCRF.' (Site from Safety).		06 Nov 2020 17:01:41
User closed query 'PV Query: Was the 1st seizure witnessed, (occurred at 09:00)? What were the circumstances surrounding the event? ' (Site from Safety).		06 Nov 2020 17:01:27
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).		06 Nov 2020 17:01:04
User closed query 'PV Query: It is reported that seizures started in Oct 2019, please confirm the date of last seizure prior to the event.' (Site from Safety).		06 Nov 2020 17:00:33
User closed query 'PV Query: - Please provide more details about history of "idiopathic seizures" and if the subject was medicated for that. ' (Site from Safety).		06 Nov 2020 17:00:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User closed query ' PV Query: It was reported that the subject's hypertension medications were adjusted. Please provide blood pressure readings and clarify if medication was increased or decreased. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:00:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User entered '61 YEAR OLD WOMAN WITH PMH OF HYPERTENSION AND ALSO PRIOR SEIZURE DISORDER OCCURRING OCT2019 and MAR2020 possible due to alcohol withdrawal, QUALIFIED TO SCREEN AND RANDOMIZE MODERNA ON 12AUG2020. NO ADVERSE REACTIONS TO VACCINE PER PHONE CALL ON 19AUG2020. HOWEVER, PATIENT DID HAVE Generalized SEIZURES (? GRAND MAL) AT 09:00 ON 23AUG2020. Patient was foaming at the mouth, eyes rolled back in her head, and she was stiff. She did shake at the end, estimates episode lasted 8 minutes, she was confused after. SHE WAS BROUGHT TO LOCAL ER BY PARAMEDICS HAD A SECOND SEIZURE AT 10:30AM ON 23AUG2020. PATIENT WAS ADMITTED TO LOCAL HOSPITAL 23-28AUG2020. SHE WAS STARTED ON ANTICONVULSANT LEVTIRACETAM 500 MG BID AND HAD NO FURTHER SEIZURES. Workup included a CT scan with and without contrast which revealed a new area of encephalomalacia within the right occipital lobe suggestive of subacute to more remote infarction but new when compared to 26FEB2020 study. Incidental 3-4 mm right superior hypophyal aneurysm. MRI showed a small area of chronic appearing encephalomalacia in the right temporal occipital region. This corresponds to the recent CT scan. An echocardiogram demonstrated reduced ejection fraction (31%) apical ballooning with severe left ventricular impairment. Also marked enlargement of the right atrium. Negative study for PFO. Labs showed mild hypokalemia and hyponatremia which improved with rehydration. These were though related to excessive alcohol intake. SHE WAS DISCHARGED TO HOME RECOVERED ON 28AUG2020 on Keppra for seizure prophylaxis, ALSO WITH ADJUSTMENTS IN HTN MEDICATIONS, AND A NEW STATIN ADDED. SAE OF generalized SEIZURES IS NOT RELATED TO STUDY MED. OR STUDY PROCEDURES ON	(b) (4), (b) (6)	05 Nov 2020 17:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
12AUG2020, BUT IS LIKELY RELATED TO HER PAST MEDICAL HISTORY OF IDIOPATHIC SEIZURES SINCE OCT2019. PATIENT is unable to travel and so cannot complete any other visits. Patient withdrew consent and stopped all study related procedures.' reason for change: Data Entry Error		
Query 'PV Query: It is reported that seizures started in Oct 2019, please confirm the date of last seizure prior to the event.' answered with 'noted' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:06:23
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' answered with 'noted' (Site from Safety).		05 Nov 2020 17:06:18
Query 'PV Query: Was the 1st seizure witnessed, (occurred at 09:00)? What were the circumstances surrounding the event? ' answered with 'updated' (Site from Safety).		05 Nov 2020 17:06:12
Query 'PV Query: Please provide specific treatment drug names of medications that were adjusted for hypertension and the new "statin" medication. Please add medications to CM eCRF.' answered with 'updated' (Site from Safety).		05 Nov 2020 17:06:05
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' answered with 'updated' (Site from Safety).		05 Nov 2020 17:05:59
Query ' PV Query: It was reported that the subject's hypertension medications were adjusted. Please provide blood pressure readings and clarify if medication was increased or decreased. ' answered with 'noted' (Site from Safety).		05 Nov 2020 17:05:53
Query 'PV Query: - Please provide more details about history of "idiopathic seizures" and if the subject was medicated for that. ' answered with 'noted' (Site from Safety).		05 Nov 2020 17:05:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It is reported that seizures started in Oct 2019, please confirm the date of last seizure prior to the event.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:43:45
User closed query 'PV Query: Idiopathic seizures was reported as medical history (since Feb 2020). Please consider adding to the medical history CRF page with onset date.		22 Oct 2020 18:03:41
' (Site from Safety).		
User closed query 'PV Query: Please provide relevant laboratory tests and/or other relevant exams (CT, MRI, EEG, etc.) performed to diagnose, confirm, and/or monitor the event. ' (Site from Safety).		22 Oct 2020 18:03:21
User closed query 'PV Query: When was the last time the subject experienced seizures before this event. ' (Site from Safety).		22 Oct 2020 18:03:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User entered '61 YEAR OLD WOMAN WITH PMH OF HYPERTENSION AND ALSO PRIOR SEIZURE DISORDER OCCURRING OCT2019, QUALIFIED TO SCREEN AND RANDOMIZE MODERNA ON 12AUG2020. NO ADVERSE REACTIONS TO VACCINE PER PHONE CALL ON 19AUG2020. HOWEVER, PATIENT DID HAVE RECURRENT SEIZURES (? GRAND MAL) AT 09:00 ON 23AUG2020. SHE WAS BROUGHT TO LOCAL ER BY PARAMEDICS HAD A SECOND SEIZURE AT 10:30AM ON 23AUG2020. PATIENT WAS ADMITTED TO LOCAL HOSPITAL 23-28AUG2020. SHE WAS STARTED ON ANTICONVULSANT LEVTIRACETAM 500MG BID AND HAD NO FURTHER SEIZURES. SHE WAS DISCHARGED TO HOME RECOVERED ON 28AUG2020, ALSO WITH ADJUSTMENTS IN HTN MEDICATIONS, AND A NEW STATIN ADDED. SAE OF RECURRENT SEIZURES IS NOT RELATED TO STUDY MED. OR STUDY PROCEDURES ON 12AUG2020, BUT IS LIKELY RELATED TO HER PAST MEDICAL HISTORY OF IDIOPATHIC SEIZURES SINCE FEB/2020. PATIENT IS DUE FOR A FOLLOW UP VISIT ON DAY 28 ON 09SEP2020. WE WILL DECIDE AT THAT TIME IF PATIENT WANTS TO CONTINUE ON THE MODERNA TRIAL. ALL HISTORY FROM PATIENTS HUSBAND. NO MEDICAL RECORDS AVAILABLE YET.'	(b) (4), (b) (6)	21 Oct 2020 20:42:34
reason for change: Data Entry Error Query 'PV Query: Idiopathic seizures was reported as medical history (since Feb 2020). Please consider adding to the medical history CRF page with onset date.	(b) (4), (b) (6)	21 Oct 2020 20:41:58
' answered with 'updated' (Site from Safety). Query 'PV Query: Please provide relevant laboratory tests and/or other relevant exams (CT, MRI, EEG, etc.) performed to diagnose, confirm, and/or monitor the event. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:41:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: When was the last time the subject experienced seizures before this event. ' answered with 'already listed in narrative' (Site from Safety). User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety). User opened query 'PV Query: Idiopathic seizures was reported as medical history (since Feb 2020). Please consider adding to the medical history CRF page with onset date.	(b) (4), (b) (6)	21 Oct 2020 20:41:24
' (Site from Safety).		02 Oct 2020 21:00:04
User opened query 'PV Query: Was the 1st seizure witnessed, (occurred at 09:00)? What were the circumstances surrounding the event? ' (Site from Safety).		10 Sep 2020 03:51:20
User opened query 'PV Query: Please provide specific treatment drug names of medications that were adjusted for hypertension and the new "statin" medication. Please add medications to CM eCRF.' (Site from Safety).		10 Sep 2020 03:51:05
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).		10 Sep 2020 03:50:16
User opened query 'PV Query: Please provide relevant laboratory tests and/or other relevant exams (CT, MRI, EEG, etc.) performed to diagnose, confirm, and/or monitor the event. ' (Site from Safety).		10 Sep 2020 03:50:00
User opened query ' PV Query: It was reported that the subject's hypertension medications were adjusted. Please provide blood pressure readings and clarify if medication was increased or decreased. ' (Site from Safety).		10 Sep 2020 03:49:25
User opened query 'PV Query: When was the last time the subject experienced seizures before this event. ' (Site from Safety).		10 Sep 2020 03:48:36
		10 Sep 2020 03:48:18

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: - Please provide more details about history of "idiopathic seizures" and if the subject was medicated for that. ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 03:48:07
Query 'Per ETRTR: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' canceled (Site from CRA).		06 Sep 2020 18:48:29
User opened query 'Per ETRTR: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).		02 Sep 2020 15:13:07
User entered '61 year old woman with PMH of hypertension and also prior seizure disorder occurring FEB/2020, qualified to screen and randomize Moderna on 12AUG2020. No adverse reactions to vaccine per phone call on 19AUG2020. However, patient did have recurrent seizures (? grand mal) at 09:00 on 23AUG2020. She was brought to local ER by paramedics had a second seizure at 10:30am on 23AUG2020. Patient was admitted to local hospital 23-28AUG2020. She was started on anticonvulsant Levetiracetam 500mg BID and had no further seizures. She was discharged to home recovered on 28AUG2020, also with adjustments in HTN medications, and a new Statin added. SAE of recurrent seizures is NOT related to study med. or study procedures on 12AUG2020, but is likely related to her past medical history of idiopathic seizures since FEB/2020. Patient is due for a follow up visit on day 28 on 09SEP2020. We will decide at that time if patient wants to continue on the Moderna trial. All history from patients husband. No medical records available yet.'		31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered 'I'	System	31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered 'I'	System	31 Aug 2020 21:17:49

US3462133

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '0'	System	31 Aug 2020 21:17:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:36:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:36:34
Data point term sent to Coder	System	05 Nov 2020 17:03:08
User entered 'right temporal CVA'	(b) (4), (b) (6)	05 Nov 2020 17:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Yes (Y)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '23 Aug 2020'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Yes (Y)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Not Related (NOT RELATED)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Not Related (NOT RELATED)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		05 Nov 2020 17:02:39
Query 'Action Taken with Investigational Product is System Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).		05 Nov 2020 17:02:39
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 17:02:39
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	05 Nov 2020 17:02:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	05 Nov 2020 17:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'l'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Unknown (UNKNOWN)'		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '0'	System	05 Nov 2020 17:02:16

US3462133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered 'I'	System	05 Nov 2020 17:02:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
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) (b) (4)	05 Nov 2020 17:04:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 17:04:23
Data point term sent to Coder	System	05 Nov 2020 17:04:11
User entered 'heart failure'	(b) (4), (b) (6)	05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Yes (Y)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '23 Aug 2020'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Yes (Y)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'No (N)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Not Related (NOT RELATED)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Not Related (NOT RELATED)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'None (NONE)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:11:43
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).		27 Jan 2021 16:31:42
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		26 Jan 2021 17:56:08
DataPoint Un-verified.		26 Jan 2021 17:56:03
User entered '0' reason for change: Data Entry Error		26 Jan 2021 17:56:03
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).		29 Nov 2020 11:48:01
DataPoint Verified.		17 Nov 2020 20:08:43
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 17:03:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 17:03:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).		05 Nov 2020 17:03:42
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:11:46
DataPoint Un-verified.		26 Jan 2021 17:56:03
User entered '1' reason for change: Data Entry Error		26 Jan 2021 17:56:03
DataPoint Verified.		17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 09:22:40
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, clarify.' answered with 'no procedure' (Site from DM).		26 Mar 2021 16:03:28
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, clarify.' (Site from DM).		17 Feb 2021 16:59:56
DataPoint Verified.		17 Nov 2020 20:08:43
User entered '0'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered 'Unknown (UNKNOWN)'		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	16 Apr 2021 22:55:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:08:43
User entered empty.		05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '0'	System	05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered 'I'	System	05 Nov 2020 17:03:42

US3462133

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:42:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:11
User entered 'Yes (Y)'		19 Oct 2020 20:54:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:56:26
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 Oct 2020 20:56:26
Data point term sent to Coder	System	19 Oct 2020 20:55:48
User entered 'atenolol'	(b) (4), (b) (6)	19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'hypertension'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '25'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'once daily (QD)'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'un UNK 2015'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)' reason for change: Data Entry Error		05 Nov 2020 17:41:36
User entered 'Yes (Y)'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '23 Aug 2020' reason for change: Data Entry Error		05 Nov 2020 17:41:36
User entered empty.		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	19 Oct 2020 20:55:39

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:58:32
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 Oct 2020 20:58:32
Data point term sent to Coder	System	19 Oct 2020 20:56:49
User entered 'multivitamin'	(b) (4), (b) (6)	19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'supplement'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'I'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'tablet (TABLET)'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'once daily (QD)'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'un UNK 2019'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	19 Oct 2020 20:56:23

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:00:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:00:24
Data point term sent to Coder	System	19 Oct 2020 20:59:56
User entered 'ibuprofen'	(b) (4), (b) (6)	19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'back pain'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '200'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'as needed (PRN)'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'un UNK 2000'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	19 Oct 2020 20:59:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
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)	05 Nov 2020 17:45:20
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 Nov 2020 17:45:20
Data point term sent to Coder	System	05 Nov 2020 17:44:05
User entered 'atorvastatin'	(b) (4), (b) (6)	05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User closed query 'Per DM CLR: This Conmed is given for the AE# 03. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:32:25
Query 'Per DM CLR: This Conmed is given for the AE# 03. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.'		26 Jan 2021 17:55:48
answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: This Conmed is given for the AE# 03. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).		06 Jan 2021 17:12:23
DataPoint Verified.		17 Nov 2020 20:10:46
User entered 'heart failure'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:44
User closed query 'Per source, Atrorvastatin was prescribed as 20mg, BID. Please clarify' (Site from CRA).		10 Feb 2021 18:16:42
Query 'Per source, Atrorvastatin was prescribed as 20mg, BID. Please clarify' answered with 'updated' (Site from CRA).		26 Jan 2021 17:55:13
DataPoint Un-verified.		26 Jan 2021 17:54:56
User entered '20' reason for change: Data Entry Error		26 Jan 2021 17:54:56
User opened query 'Per source, Atrorvastatin was prescribed as 20mg, BID. Please clarify' (Site from CRA).		17 Nov 2020 20:16:40
DataPoint Verified.		17 Nov 2020 20:10:46
User entered '40'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:46
User closed query 'Per source, Atrorvastatin was prescribed as 20mg, BID. Please clarify' (Site from CRA).		10 Feb 2021 18:16:40
DataPoint Un-verified.		26 Jan 2021 17:55:28
User entered 'twice daily (BID)' reason for change: Data Entry Error		26 Jan 2021 17:55:28
Query 'Per source, Atrorvastatin was prescribed as 20mg, BID. Please clarify' answered with 'updated' (Site from CRA).		26 Jan 2021 17:55:09
User opened query 'Per source, Atrorvastatin was prescribed as 20mg, BID. Please clarify' (Site from CRA).		17 Nov 2020 20:17:08
DataPoint Verified.		17 Nov 2020 20:10:46
User entered 'once daily (QD)'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:16:54
User closed query 'Per source, start date was 23Aug2020. Please clarify. ' (Site from CRA).		10 Feb 2021 18:16:51
Query 'Per source, start date was 23Aug2020. Please clarify. ' answered with 'updated' (Site from CRA).		26 Jan 2021 17:55:01
DataPoint Un-verified.		26 Jan 2021 17:54:56
User entered '23 Aug 2020' reason for change: Data Entry Error		26 Jan 2021 17:54:56
User opened query 'Per source, start date was 23Aug2020. Please clarify. ' (Site from CRA).		17 Nov 2020 20:17:52
DataPoint Verified.		17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)' reason for change: Data Entry Error		06 Nov 2020 19:49:56
User entered 'No (N)'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 19:49:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 19:49:56
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	05 Nov 2020 17:43:05
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '2'	System	26 Jan 2021 17:55:28
User entered '1'	System	05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:43:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 17:46:20
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 Nov 2020 17:46:20
Data point term sent to Coder	System	05 Nov 2020 17:45:06
User entered 'aspirin'	(b) (4), (b) (6)	05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'cardiac prophylaxis'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '81'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'once daily (QD)'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '27 Aug 2020'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:44:22

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:27:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:27:39
Data point term sent to Coder	System	05 Nov 2020 17:47:08
User entered 'levetiracetam'	(b) (4), (b) (6)	05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'generalized seizures'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '500'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'twice daily (BID)'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:17:21
User closed query 'Per source Con Meds Log, start date was 23Aug2020. Please clarify. ' (Site from CRA).		10 Feb 2021 18:17:18
Query 'Per source Con Meds Log, start date was 23Aug2020. Please clarify. ' answered with 'updated' (Site from CRA).		26 Jan 2021 17:57:00
DataPoint Un-verified.		26 Jan 2021 17:56:55
User entered '23 Aug 2020' reason for change: Data Entry Error		26 Jan 2021 17:56:55
User opened query 'Per source Con Meds Log, start date was 23Aug2020. Please clarify. ' (Site from CRA).		17 Nov 2020 20:19:06
DataPoint Verified.		17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User closed query 'Per DM CLR-RQ: Response noted. However, per AE#1 GENERALIZED SEIZURES, condition resolved on 26AUG2020. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:13:33
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
Query 'Per DM CLR-RQ: Response noted. However, per AE#1 GENERALIZED SEIZURES, condition resolved on 26AUG2020. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:33
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 20:40:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:40:17
User opened query 'Per DM CLR-RQ: Response noted. However, per AE#1 GENERALIZED SEIZURES, condition resolved on 26AUG2020. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	08 Mar 2021 09:05:13
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). 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 'this is correct' (Site from DM).	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
	(b) (4), (b) (6)	02 Feb 2021 11:41:56
	(b) (4), (b) (6)	26 Jan 2021 17:57:08

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 17:13:31
		17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		13 Apr 2021 16:29:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:40:17
Signature has been broken.		12 Apr 2021 20:40:17
User entered '26 Aug 2020' reason for change: Data Entry Error		12 Apr 2021 20:40:17
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '2'	System	05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:46:58

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:24:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:24:59
Data point term sent to Coder	System	26 Jan 2021 17:58:56
Coding entries removed.	(b) (4), (b) (6)	26 Jan 2021 17:58:13
DataPoint Verified.		17 Nov 2020 20:10:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:48:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:48:24
Data point term sent to Coder	System	05 Nov 2020 17:48:11
User entered 'ondansetron'	(b) (4), (b) (6)	05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).		19 Apr 2021 15:13:17
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'med. was given to patient for this indication' (Site from DM).		12 Apr 2021 20:41:58
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).		08 Mar 2021 09:06:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:19:22
User closed query 'Nausea is not noted in Med Hx or AE pages. Please clarify indication or add as AE if required. ' (Site from CRA).		10 Feb 2021 18:19:20
Query 'Nausea is not noted in Med Hx or AE pages. Please clarify indication or add as AE if required. ' answered with 'updated' (Site from CRA).		26 Jan 2021 17:58:17
DataPoint Un-verified.		26 Jan 2021 17:58:13
User entered 'heart failure' reason for change: Data Entry Error		26 Jan 2021 17:58:13
User opened query 'Nausea is not noted in Med Hx or AE pages. Please clarify indication or add as AE if required. ' (Site from CRA).		17 Nov 2020 20:23:00
DataPoint Verified.		17 Nov 2020 20:10:46
User entered 'nausea'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '4'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'as needed (PRN)'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '02 Sep 2020'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:47:57

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'hypertension'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '25'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'twice daily (BID)'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '23 Aug 2020'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '2'	System	05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:48:54

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
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 HYPERTENSION should be recorded, update Con Med indication or provide clarification. ' (Site from DM). 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 HYPERTENSION should be recorded, update Con Med indication or provide clarification. ' answered with 'not worsening' (Site from DM). 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 HYPERTENSION should be recorded, update Con Med indication or provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:30:20 26 Jan 2021 17:58:43 06 Jan 2021 17:14:58 17 Nov 2020 20:10:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 17:51:20
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 Nov 2020 17:51:20
Data point term sent to Coder	System	05 Nov 2020 17:50:12
User entered 'lisinopril'	(b) (4), (b) (6)	05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'hypertension'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '2.5'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'once daily (QD)'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '23 Aug 2020'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:49:41

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN ALCOHOL DEPENDENCE, PRODUCT: DISULFIRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:17:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:17:33
Data point term sent to Coder	System	05 Nov 2020 17:51:13
User entered 'disulfiram'	(b) (4), (b) (6)	05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
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) (4), (b) (6)	27 Jan 2021 10:01:53
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 'no ae' (Site from DM).		26 Jan 2021 17:58:54
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).		06 Jan 2021 17:15:34
DataPoint Verified.		17 Nov 2020 20:10:46
User entered 'alcohol cessation'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '250'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'once daily (QD)'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:50:24

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 18:00:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 18:00:58
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	26 Jan 2021 17:59:59 26 Jan 2021 17:59:21
DataPoint Verified.		17 Nov 2020 20:10:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:52:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:52:21
Data point term sent to Coder User entered 'nicotine patch'	System (b) (4), (b) (6)	05 Nov 2020 17:51:14 05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User closed query 'Per DM CLR: Please note that there is no AE that matches Con Med #11 and # 12 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) (4), (b) (6)	27 Jan 2021 10:02:02
Query 'Per DM CLR: Please note that there is no AE that matches Con Med #11 and # 12 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 'no ae' (Site from DM).		26 Jan 2021 17:59:03
User opened query 'Per DM CLR: Please note that there is no AE that matches Con Med #11 and # 12 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).		06 Jan 2021 17:15:54
DataPoint Verified.		17 Nov 2020 20:10:46
User entered 'smoking cessation'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '14'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'once daily (QD)'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:20:35
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		27 Jan 2021 10:02:55
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).		26 Jan 2021 17:59:26
DataPoint Un-verified.		26 Jan 2021 17:59:21
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error		26 Jan 2021 17:59:21
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		06 Jan 2021 17:16:08
DataPoint Verified.		17 Nov 2020 20:10:46
User entered 'Topical (TOPICAL)'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '1'	System	05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered '804 (804)'	System	05 Nov 2020 17:51:05

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 17:53:22
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 Nov 2020 17:53:22
Data point term sent to Coder	System	05 Nov 2020 17:52:15
User entered 'nicotine gum'	(b) (4), (b) (6)	05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'smoking cessation'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '2'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'mg (mg)'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'as needed (PRN)'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Oral (ORAL)'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '26 Aug 2020'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered '0'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'Yes (Y)'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered empty.		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:10:46
User entered 'No (N)'		05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User entered empty.	System	05 Nov 2020 17:51:48

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:42:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:23:16
User entered 'Yes (Y)' reason for change: Data Entry Error		21 Oct 2020 20:26:29
User entered 'No (N)' reason for change: Data Entry Error		19 Oct 2020 20:54:50
User entered 'Yes (Y)'		19 Oct 2020 20:54:12

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:48
User entered '23 Aug 2020'		21 Oct 2020 20:27:43

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:50
User entered 'Labs'		21 Oct 2020 20:27:43

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:53
User entered 'Adverse Event (AE)'		21 Oct 2020 20:27:43

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:45:52
User entered empty.		21 Oct 2020 20:27:43

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:21
User entered '24 Aug 2020' reason for change: Data Entry Error		21 Oct 2020 20:31:33
User entered '23 Aug 2020'		21 Oct 2020 20:28:03

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:47:23
User entered 'CT angiogram HEAD' reason for change: Data Entry Error		21 Oct 2020 20:31:33
User entered 'CT Head'		21 Oct 2020 20:28:03

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:53:53
User entered 'Adverse Event (AE)'		21 Oct 2020 20:28:03

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:53:56
User entered empty.		21 Oct 2020 20:28:03

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:19
User entered '25 Aug 2020' reason for change: Data Entry Error		21 Oct 2020 20:33:19
User entered '24 Aug 2020'		21 Oct 2020 20:28:20

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:20
User entered 'MRI BRAIN with and without contrast' reason for change: Data Entry Error		21 Oct 2020 20:33:19
User entered 'MRI brain'		21 Oct 2020 20:28:20

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:21
User entered 'Adverse Event (AE)'		21 Oct 2020 20:28:20

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.		21 Oct 2020 20:28:20

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:52
User entered '23 Aug 2020'		21 Oct 2020 20:32:30

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:53
User entered 'CT head without contrast'		21 Oct 2020 20:32:30

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:59
User entered 'Adverse Event (AE)'		21 Oct 2020 20:32:30

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:01
User entered empty.		21 Oct 2020 20:32:30

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:19
User entered '24 Aug 2020'		21 Oct 2020 20:33:56

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:20
User entered 'CT angiogram neck'		21 Oct 2020 20:33:56

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:22
User entered 'Adverse Event (AE)'		21 Oct 2020 20:33:56

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:25
User entered empty.		21 Oct 2020 20:33:56

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:42
User entered '25 Aug 2020'		21 Oct 2020 20:34:46

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:44
User entered 'Echo 2d complete doppler color flow'		21 Oct 2020 20:34:46

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:46
User entered 'Adverse Event (AE)'		21 Oct 2020 20:34:46

US3462133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:47
User entered empty.		21 Oct 2020 20:34:46

US3462133

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:27

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:18:04
User closed query 'Per progress notes, date 14-SEP-2021 notes withdrawing from study due to unstable health. Please clarify date of dosing discontinuation' (Site from CRA).		19 Apr 2021 18:18:02
User closed query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System).	System	14 Apr 2021 16:32:32
User closed query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	14 Apr 2021 16:32:32
User entered '12 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:32:32
User opened query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System).	System	14 Apr 2021 16:32:13
User opened query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	14 Apr 2021 16:32:13
User entered '12 Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:32:13
Query 'Per progress notes, date 14-SEP-2021 notes withdrawing from study due to unstable health. Please clarify date of dosing discontinuation' answered with 'updated' (Site from CRA).		13 Apr 2021 16:34:20
DataPoint Un-verified.		13 Apr 2021 16:34:16
Signature has been broken.		13 Apr 2021 16:34:16
User entered '14 Sep 2020' reason for change: Data Entry Error		13 Apr 2021 16:34:16
DataPoint Verified.		13 Apr 2021 16:27:07

US3462133

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:27

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per progress notes, date 14-SEP-2021 notes withdrawing from study due to unstable health. Please clarify date of dosing discontinuation' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) (b) (4)	13 Apr 2021 16:27:04
	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:01

US3462133

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:01

US3462133

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:27

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)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Patient withdrew consent due to unstable health.'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:01

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:10:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:17:10
User closed query 'Per progress notes, date 14-SEP-2021 notes withdrawing from study due to unstable health. Please clarify date of dosing discontinuation ' (Site from CRA).		19 Apr 2021 18:17:06
Query 'Per progress notes, date 14-SEP-2021 notes withdrawing from study due to unstable health. Please clarify date of dosing discontinuation ' answered with 'updated' (Site from CRA).		13 Apr 2021 16:34:07
DataPoint Un-verified.		13 Apr 2021 16:34:01
Signature has been broken.		13 Apr 2021 16:34:01
User entered '14 Sep 2020' reason for change: Data Entry Error		13 Apr 2021 16:34:01
DataPoint Verified.		13 Apr 2021 16:27:38
User opened query 'Per progress notes, date 14-SEP-2021 notes withdrawing from study due to unstable health. Please clarify date of dosing discontinuation ' (Site from CRA).		13 Apr 2021 16:27:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

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)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'Patient withdrew consent due to unstable health.'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:46:57
DataPoint Verified.		13 Apr 2021 16:27:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:07:32

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'USA-US093-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Amendment Manager: Data point set to conformant.	(b) (4)	
Reviewed for Safety.	System	19 Sep 2020 06:44:31
	(b) (4), (b) (6)	01 Sep 2020 18:22:50
User entered 'US' (non-conformant).		
	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '4'	System	06 Nov 2020 17:05:03
User entered '3'	System	28 Oct 2020 13:53:06
User entered '2'	System	22 Oct 2020 18:05:05
User entered '1'	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'USA-US093-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Amendment Manager: Data point set to conformant.	(b) (4)	
Reviewed for Safety.	System	19 Sep 2020 06:44:31
	(b) (4), (b) (6)	01 Sep 2020 18:22:50
User entered 'US' (non-conformant).		
	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '4'	System	06 Nov 2020 17:05:03
User entered '3'	System	28 Oct 2020 13:53:06
User entered '2'	System	22 Oct 2020 18:05:05
User entered '1'	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:42:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '01/Sep/2020 14:22'	(b) (4) System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:42:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
User entered 'I'		01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'USA-US093-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Amendment Manager: Data point set to conformant.	(b) (4)	
Reviewed for Safety.	System	19 Sep 2020 06:44:31
	(b) (4), (b) (6)	01 Sep 2020 18:22:50
User entered 'US' (non-conformant).		
	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '4'	System	06 Nov 2020 17:05:03
User entered '3'	System	28 Oct 2020 13:53:06
User entered '2'	System	22 Oct 2020 18:05:05
User entered '1'	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:42:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '22/Oct/2020 18:05'	(b) (4) System	22 Oct 2020 18:05:05

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:42:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:05:53
User entered 'I'		22 Oct 2020 18:05:05

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'USA-US093-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Amendment Manager: Data point set to conformant.	(b) (4)	
Reviewed for Safety.	System	19 Sep 2020 06:44:31
	(b) (4), (b) (6)	01 Sep 2020 18:22:50
User entered 'US' (non-conformant).		
	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '4'	System	06 Nov 2020 17:05:03
User entered '3'	System	28 Oct 2020 13:53:06
User entered '2'	System	22 Oct 2020 18:05:05
User entered '1'	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:42:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '28/Oct/2020 13:53'	(b) (4) System	28 Oct 2020 13:53:06

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:42:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:04:48
User entered 'I'		28 Oct 2020 13:53:06

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'USA-US093-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'Yes (Y)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered 'No (N)'	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:04:53
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:57
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:22:34
User entered (b) (6)	System	01 Sep 2020 18:21:51

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
Amendment Manager: Data point set to conformant.	(b) (4)	
Reviewed for Safety.	System	19 Sep 2020 06:44:31
	(b) (4), (b) (6)	01 Sep 2020 18:22:50
User entered 'US' (non-conformant).		
	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '4'	System	06 Nov 2020 17:05:03
User entered '3'	System	28 Oct 2020 13:53:06
User entered '2'	System	22 Oct 2020 18:05:05
User entered '1'	System	01 Sep 2020 18:22:41

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:42:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered '06/Nov/2020 12:04'	(b) (4) System	06 Nov 2020 17:05:03

US3462133

Folder: SAE USA-US093-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:42:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:26:08
DataPoint Verified.		19 Apr 2021 22:12:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:49:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:05:03