

US3272070 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:50:34

All time stamps listed in this document are displayed in GMT

US3272070

Form: Participant Creation

Generated On: 26 Nov 2020 10:50:34

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

Generated On: 26 Nov 2020 10:50:34

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

Date of Informed Consent (<i>dd MMM yyyy</i>)	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:50:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:50:34

[Were any significant conditions reported?](#)

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

Condition	DIABETES MELLITUS TYPE 2
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 (2)

Generated On: 26 Nov 2020 10:50:34

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:24 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:24
Height (<i>xxx.x</i>)	175 cm
Weight (<i>xxx.x</i>)	112.4 kg
BMI (<i>xxx.x</i>)	36.70204 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

Generated On: 26 Nov 2020 10:50:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

(b) (6)
, 3TO 4 OUTINGS
A WEEK (FUNERALS,
HOLIDAYS, GROUP MEETINGS)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

v6.020 DTW (1102)

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

Generated On: 26 Nov 2020 10:50:34

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 185111

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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)	6 AUG 2020
Time of assessment (00:00-23:59)	16:24 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 16:24
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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)	6 AUG 2020
Time of assessment (00:00-23:59)	18:30 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 18:30
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	06 AUG 2020
What was the treatment time? (00:00-23:59)	17:57 (24 HR)
Treatment Date and Time (derived)	06 AUG 2020 17:57
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 10:50:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	6 AUG 2020
Collection time (<i>00:00-23:59</i>)	17:04 (24 HR)
Collection date and time (derived)	6 AUG 2020 17:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:34

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:51	6 AUG 2020 16:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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: 26 Nov 2020 10:50:34

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 18:40

PC Open Date & Time

06 AUG 2020 18:17

PC Close Date & Time

06 AUG 2020 20:47

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 06 AUG 2020 21:42

PC Close Date & Time 07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

96.4 °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

07 AUG 2020 17:23

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

09 AUG 2020 16:22

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

96.5 °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

10 AUG 2020 12:04

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:07

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 18:40

PC Open Date & Time

06 AUG 2020 18:17

PC Close Date & Time

06 AUG 2020 20:47

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

06 AUG 2020 21:42

PC Close Date & Time

07 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

07 AUG 2020 17:25

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

08 AUG 2020 12:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

09 AUG 2020 16:23

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

10 AUG 2020 12:04

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

11 AUG 2020 12:16

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

12 AUG 2020 13:07

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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 ☐

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 18:41
PC Open Date & Time	06 AUG 2020 18:17
PC Close Date & Time	06 AUG 2020 20:47

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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 ☐

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 21:42

PC Close Date & Time

07 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 17:26
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

		Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 12:05	
PC Open Date & Time	08 AUG 2020 12:00	
PC Close Date & Time	09 AUG 2020 11:59	

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 16:24
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:08
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3272070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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)	3 SEP 2020
Time of assessment (00:00-23:59)	13:56 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 13:56
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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)	3 SEP 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3272070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	3 SEP 2020
What was the treatment time? (00:00-23:59)	14:52 (24 HR)
Treatment Date and Time (derived)	3 SEP 2020 14:52
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3272070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:19 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:34

Collection date (<i>dd MMM yyyy</i>)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	3 SEP 2020 14:05
Nasopharyngeal Swab 2	No		

US3272070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:26

PC Open Date & Time

03 SEP 2020 15:12

PC Close Date & Time

03 SEP 2020 17:42

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 03 SEP 2020 18:37

PC Close Date & Time 04 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

94.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:14

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

94.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

07 SEP 2020 12:05

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

94.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 14:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

03 SEP 2020 15:30

PC Open Date & Time

03 SEP 2020 15:12

PC Close Date & Time

03 SEP 2020 17:42

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 18:37

PC Close Date & Time

04 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

05 SEP 2020 12:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

06 SEP 2020 16:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

07 SEP 2020 12:06

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

08 SEP 2020 12:03

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

09 SEP 2020 14:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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 ☐

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:31
PC Open Date & Time	03 SEP 2020 15:12
PC Close Date & Time	03 SEP 2020 17:42

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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 ☐

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 18:37

PC Close Date & Time

04 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

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 ☐

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

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 ☐

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:06
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:04
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

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 ☒

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 14:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

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 _____

US3272070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3272070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

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.

US3272070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

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/>

US3272070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272070

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:50:34

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

US3272070

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:50:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3272070

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:50:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

AEID	USA-US070-2020-MRNA-1273-P30 1000003
Adverse event	MYOCARDIAL INFARCTION
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)	1 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	117 of 1377

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

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

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:50:34

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

Yes ☒

No ☐

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

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	AMITRIPTYLINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETIC NEUROPATHY.
Dose per administration	75
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	CHOLECALCIFEROL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DIABETES MELLITUS TYPE 2
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	INSULIN 500 (PEN)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES MELLITUS TYPE 2
Dose per administration	100
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNITS
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	LOSARTAN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIABETES MELLITUS TYPE 2
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

	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	1987
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"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	SIMVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	CYANOCOBALAMIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	EMPAGLIFLOZIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES MELLITUS TYPE 2
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

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 (10)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CARDIAC PROPHYLAXIS
Dose per administration	21
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

	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	1987
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)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	ASPIRIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	300
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	TITRATION DRIP Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	VERAPAMIL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	2.5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRA ARTERIAL	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	NITROGLYCERIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	200
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRA ARTERIAL	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	999
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	HEPARIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	1000
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRA ARTERIAL	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	PHENYLEPHRINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	100
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	EPINEPHRINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	IOPAMIDOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	95
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	NOREPINEPHRINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	30
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	TITRATION DRIP
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

Name of Medication	VASOPRESSIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MYOCARDIAL INFARCTION
Dose per administration	.04
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input checked="" type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:50:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:50:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 OCT 2020	INTUBATION	Adverse Event	
01 OCT 2020	MECHANICAL VENTILATION	Adverse Event	
01 OCT 2020	ARTERIAL LINE INSERTION	Adverse Event	
01 OCT 2020	CENTRAL VENOUS CATHETER INSERTION	Adverse Event	
01 OCT 2020	CORONARY CATHETERIZATION	Adverse Event	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

Date of study discontinuation/completion (dd MMM yyyy) 01 OCT 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input checked="" 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 type="checkbox"/>
Other	<input type="checkbox"/>

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

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 01 OCT 2020

Was autopsy performed?

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

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:50:34

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:54
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

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:50:34

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/OCT/2020 13:13
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

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:50:34

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 14:43
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

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:50:34

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:50
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

US3272070 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272070

Form: Participant Creation

Generated On: 26 Nov 2020 10:50:34

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3272070'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	06 Aug 2020 22:14:18

US3272070

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:45:23

US3272070

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:46
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:19

US3272070

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 19:45:23

US3272070

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 19:45:23

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:20

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '74'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '74'	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered 'Male (M)'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:34

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:46:26

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered '06 Aug 2020'	Ashley Bell (b) (4)	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered 'Amendment 1 (1)'	Ashley Bell (b) (4)	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered 'Yes (Y)'	Ashley Bell (b) (4)	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered 'No (N)'	Ashley Bell (b) (4)	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:19

US3272070

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:42
User entered 'Yes (Y)'	Ashley Bell (b) (4)	06 Aug 2020 23:12:45

US3272070

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:50:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User closed query 'Medical records show subject also has a history of COPD. Consider adding to the Medical history CRF.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:06:16
Query 'Medical records show subject also has a history of COPD. Consider adding to the Medical history CRF.' answered with 'updated' (Site from CRA).	Ashley Bell (b) (4)	21 Oct 2020 00:54:46
User opened query 'Medical records show subject also has a history of COPD. Consider adding to the Medical history CRF.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:48:35
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:47:55

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:49:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:49:47
Data point term sent to Coder	System	28 Aug 2020 19:48:28
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'UN UNK 2000'	(b) (4), (b) (6)	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '2000'	System	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:48:24

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:51:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:51:54
Data point term sent to Coder	System	28 Aug 2020 19:50:33
User entered 'hypertension'	(b) (4), (b) (6)	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'UN UNK 2017'	(b) (4), (b) (6)	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '2017'	System	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:49:49

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:52:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:52:16
Data point term sent to Coder	System	28 Aug 2020 19:50:33
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'UN UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '2010'	System	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:50:08

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 00:55:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 00:55:24
Data point term sent to Coder	System	21 Oct 2020 00:54:28
User entered 'COPD'	Ashley Bell (b) (4)	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered 'un UNK 2020'	Ashley Bell (b) (4)	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	Ashley Bell (b) (4)	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:54:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 00:54:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	21 Oct 2020 00:54:07
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:54:02
User entered empty.	Ashley Bell (b) (4)	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered empty.	Ashley Bell (b) (4)	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User entered '0'	Ashley Bell (b) (4)	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 00:54:02

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:34:50
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 16:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:12:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered '06 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered '16:24' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '16:24'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 16:24'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered '6 Aug 2020 16:24'	System	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered '175' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '175' cm	(b) (4), (b) (6)	28 Aug 2020 19:51:25
DataPoint set to visible.	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered '112.4' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '112.4' kg	(b) (4), (b) (6)	28 Aug 2020 19:51:25
DataPoint set to visible.	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '36.70204'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered '36.70204'	System	28 Aug 2020 19:51:25
DataPoint set to visible.	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered 'kg/m2'	System	28 Aug 2020 19:51:25
DataPoint set to visible.	System	06 Aug 2020 23:13:05

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:34:53
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 16:51:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:12:09
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:12:09
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:48:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:41:23
User entered '36.9' C	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered 'Other (Other)'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered 'temporal'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '86'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered 'bpm'	System	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Aug 2020 19:51:35
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Aug 2020 19:51:35
User entered '24' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 19:51:35
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Aug 2020 19:51:25
User entered '86'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered 'breaths/min'	System	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '122'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered 'mmHg'	System	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 16:51:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:48:40
User entered '66'	(b) (4), (b) (6)	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 16:51:18
User entered empty.	System	15 Sep 2020 23:48:40
User entered 'mmHg'	System	28 Aug 2020 19:51:25

US3272070

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:52:41

US3272070

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:10
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:26:07
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 21:38:59
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:52:41

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered (b) (6), 3to 4 outings a week (funerals, holidays, group meetings)'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:34

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:55:32

US3272070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	29 Oct 2020 19:52:53
DataPoint Un-verified.	Ashley Bell (b) (4)	29 Oct 2020 19:52:49
User entered '06 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	29 Oct 2020 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:49
User opened query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:48:31
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:55:32

US3272070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 19:55:32

US3272070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 19:55:32

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:21

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:44:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:44:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 22:14:21
User entered '185111' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:21

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:21

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:56:01

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:56:01

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:56:01

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:56:01

US3272070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:34

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:56:01

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:34

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:27:59
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:19:58
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '175' cm	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:34

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:15
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:20:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '112.4' kg	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:34

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:27:59
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:19:58
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '175' cm	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:34

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:15
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:20:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '112.4' kg	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '16:24'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '6 Aug 2020 16:24'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '36.9' C	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered 'Other (Other)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered 'temporal'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '86'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '24'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '122'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '66'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:34

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:27:59
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:19:58
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '175' cm	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:34

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:28:15
Query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:20:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:19:49
User opened query 'Per CDM: If subject is screened and randomized same day, site to enter "ND" into field as height and weight is recorded on screening visit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:30:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '112.4' kg	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '18:30'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '6 Aug 2020 18:30'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '36.8' C	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered 'Other (Other)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered 'temporal'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '80'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '20'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '120'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:59
User entered '74'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 19:58:10

US3272070

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:58:21

US3272070

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:03
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:58:21

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	15 Aug 2020 15:00:17
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	15 Aug 2020 15:00:17
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	06 Aug 2020 23:13:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User entered '06 Aug 2020'	Ashley Bell (b) (4)	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User entered '17:57'	Ashley Bell (b) (4)	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '06 Aug 2020 17:57'	System	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 15:00:17
User entered empty.	Ashley Bell (b) (4)	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:08
User entered 'ONCE'	System	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 23:13:28

US3272070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:58:47

US3272070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:13
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:58:47

US3272070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:13
User entered '17:04'	(b) (4), (b) (6)	28 Aug 2020 19:58:47

US3272070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '6 Aug 2020 17:04'	System	28 Aug 2020 19:58:47

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered '16:51'	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '6 Aug 2020 16:51'	System	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 19:59:09

US3272070

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:59:14

US3272070

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 19:59:14

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:39:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c627146d-4b87-4813-aa36-9804f8381e17'	System	06 Aug 2020 23:40:07
User entered 'Yes (Y)'	System	06 Aug 2020 23:40:07

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:39:47', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c627146d-4b87-4813-aa36-9804f8381e17'	System	06 Aug 2020 23:40:07
User entered '98.2'	System	06 Aug 2020 23:40:07

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:39:54', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c627146d-4b87-4813-aa36-9804f8381e17'	System	06 Aug 2020 23:40:07
User entered 'No (N)'	System	06 Aug 2020 23:40:07

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:03', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c627146d-4b87-4813-aa36-9804f8381e17'	System	06 Aug 2020 23:40:07
User entered '06 Aug 2020 18:40'	System	06 Aug 2020 23:40:07

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 18:17'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 20:47'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 21:42'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 2'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:22:14', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '4e2bf9dd-f3da-444d-909a-c369afa0c58d'	System	07 Aug 2020 22:23:41
User entered 'Yes (Y)'	System	07 Aug 2020 22:23:41

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:23:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '4e2bf9dd-f3da-444d-909a-c369afa0c58d'	System	07 Aug 2020 22:23:41
User entered '96.4'	System	07 Aug 2020 22:23:41

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:23:17', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '4e2bf9dd-f3da-444d-909a-c369afa0c58d'	System	07 Aug 2020 22:23:41
User entered 'No (N)'	System	07 Aug 2020 22:23:41

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:23:38', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '4e2bf9dd-f3da-444d-909a-c369afa0c58d'	System	07 Aug 2020 22:23:41
User entered '07 Aug 2020 17:23'	System	07 Aug 2020 22:23:41

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 3'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:03:38', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8d518e63-7dec-4e7a-b728-770c3af05b4f'	System	08 Aug 2020 17:04:13
User entered 'Yes (Y)'	System	08 Aug 2020 17:04:13

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:03:51', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8d518e63-7dec-4e7a-b728-770c3af05b4f'	System	08 Aug 2020 17:04:13
User entered '96.2'	System	08 Aug 2020 17:04:13

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:03:56', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8d518e63-7dec-4e7a-b728-770c3af05b4f'	System	08 Aug 2020 17:04:13
User entered 'No (N)'	System	08 Aug 2020 17:04:13

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:04:08', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8d518e63-7dec-4e7a-b728-770c3af05b4f'	System	08 Aug 2020 17:04:13
User entered '08 Aug 2020 12:04'	System	08 Aug 2020 17:04:13

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 4'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:22:01', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd3504ff9-c833-4315-8689-f8674e1a037e'	System	09 Aug 2020 21:22:32
User entered 'Yes (Y)'	System	09 Aug 2020 21:22:32

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:22:10', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd3504ff9-c833-4315-8689-f8674e1a037e'	System	09 Aug 2020 21:22:32
User entered '96.3'	System	09 Aug 2020 21:22:32

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:22:14', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd3504ff9-c833-4315-8689-f8674e1a037e'	System	09 Aug 2020 21:22:32
User entered 'No (N)'	System	09 Aug 2020 21:22:32

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:22:27', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd3504ff9-c833-4315-8689-f8674e1a037e'	System	09 Aug 2020 21:22:32
User entered '09 Aug 2020 16:22'	System	09 Aug 2020 21:22:32

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 5'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:03:42', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '31810255-69d3-4bcf-83a9-ff227934f53d'	System	10 Aug 2020 17:04:09
User entered 'Yes (Y)'	System	10 Aug 2020 17:04:09

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:03:51', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '31810255-69d3-4bcf-83a9-ff227934f53d'	System	10 Aug 2020 17:04:09
User entered '96.5'	System	10 Aug 2020 17:04:09

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:03:57', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '31810255-69d3-4bcf-83a9-ff227934f53d'	System	10 Aug 2020 17:04:09
User entered 'No (N)'	System	10 Aug 2020 17:04:09

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:07', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '31810255-69d3-4bcf-83a9-ff227934f53d'	System	10 Aug 2020 17:04:09
User entered '10 Aug 2020 12:04'	System	10 Aug 2020 17:04:09

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 6'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:14:55', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '29e04e45-eaee-45e2-874f-3d51df3bd984'	System	11 Aug 2020 17:15:27
User entered 'Yes (Y)'	System	11 Aug 2020 17:15:27

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:05', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '29e04e45-eaee-45e2-874f-3d51df3bd984'	System	11 Aug 2020 17:15:27
User entered '95.6'	System	11 Aug 2020 17:15:27

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:11', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '29e04e45-eaee-45e2-874f-3d51df3bd984'	System	11 Aug 2020 17:15:27
User entered 'No (N)'	System	11 Aug 2020 17:15:27

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:22', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '29e04e45-eaee-45e2-874f-3d51df3bd984'	System	11 Aug 2020 17:15:27
User entered '11 Aug 2020 12:15'	System	11 Aug 2020 17:15:27

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 7'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:06:46', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'cdabbace-b7e9-4ce2-8290-f73c2a303db7'	System	12 Aug 2020 18:07:20
User entered 'Yes (Y)'	System	12 Aug 2020 18:07:20

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:04', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'cdabbace-b7e9-4ce2-8290-f73c2a303db7'	System	12 Aug 2020 18:07:20
User entered '96.1'	System	12 Aug 2020 18:07:20

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:10', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'cdabbace-b7e9-4ce2-8290-f73c2a303db7'	System	12 Aug 2020 18:07:20
User entered 'No (N)'	System	12 Aug 2020 18:07:20

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:18', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'cdabbace-b7e9-4ce2-8290-f73c2a303db7'	System	12 Aug 2020 18:07:20
User entered '12 Aug 2020 13:07'	System	12 Aug 2020 18:07:20

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:15', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '712a3721-afa2-4bc3-bf7c-ca9d10db208a'	System	06 Aug 2020 23:40:42
User entered 'None (1)'	System	06 Aug 2020 23:40:42

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:21', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '712a3721-afa2-4bc3-bf7c-ca9d10db208a'	System	06 Aug 2020 23:40:42
User entered 'No (N)'	System	06 Aug 2020 23:40:42

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:24', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '712a3721-afa2-4bc3-bf7c-ca9d10db208a'	System	06 Aug 2020 23:40:42
User entered 'No (N)'	System	06 Aug 2020 23:40:42

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '712a3721-afa2-4bc3-bf7c-ca9d10db208a'	System	06 Aug 2020 23:40:42
User entered 'None (1)'	System	06 Aug 2020 23:40:42

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:39', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '712a3721-afa2-4bc3-bf7c-ca9d10db208a'	System	06 Aug 2020 23:40:42
User entered '06 Aug 2020 18:40'	System	06 Aug 2020 23:40:42

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 18:17'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 20:47'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 21:42'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 2'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:24:45', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'dd64e09a-e6b0-4d5e-9d8b-c1256dd038c0'	System	07 Aug 2020 22:25:08
User entered 'None (1)'	System	07 Aug 2020 22:25:08

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:24:17', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'dd64e09a-e6b0-4d5e-9d8b-c1256dd038c0'	System	07 Aug 2020 22:25:08
User entered 'No (N)'	System	07 Aug 2020 22:25:08

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:24:21', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'dd64e09a-e6b0-4d5e-9d8b-c1256dd038c0'	System	07 Aug 2020 22:25:08
User entered 'No (N)'	System	07 Aug 2020 22:25:08

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:24:30', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'dd64e09a-e6b0-4d5e-9d8b-c1256dd038c0'	System	07 Aug 2020 22:25:08
User entered 'None (1)'	System	07 Aug 2020 22:25:08

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:05', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'dd64e09a-e6b0-4d5e-9d8b-c1256dd038c0'	System	07 Aug 2020 22:25:08
User entered '07 Aug 2020 17:25'	System	07 Aug 2020 22:25:08

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 3'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:04:27', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '71469c16-40f2-4349-9851-1a7df6385f87'	System	08 Aug 2020 17:05:05
User entered 'None (1)'	System	08 Aug 2020 17:05:05

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:04:32', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '71469c16-40f2-4349-9851-1a7df6385f87'	System	08 Aug 2020 17:05:05
User entered 'No (N)'	System	08 Aug 2020 17:05:05

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:04:36', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '71469c16-40f2-4349-9851-1a7df6385f87'	System	08 Aug 2020 17:05:05
User entered 'No (N)'	System	08 Aug 2020 17:05:05

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:04:44', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '71469c16-40f2-4349-9851-1a7df6385f87'	System	08 Aug 2020 17:05:05
User entered 'None (1)'	System	08 Aug 2020 17:05:05

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:04:59', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '71469c16-40f2-4349-9851-1a7df6385f87'	System	08 Aug 2020 17:05:05
User entered '08 Aug 2020 12:04'	System	08 Aug 2020 17:05:05

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 4'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:22:53', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '0d35f32f-eecf-4649-a27c-69ed26d70bea'	System	09 Aug 2020 21:23:21
User entered 'None (1)'	System	09 Aug 2020 21:23:21

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:22:57', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '0d35f32f-eecf-4649-a27c-69ed26d70bea'	System	09 Aug 2020 21:23:21
User entered 'No (N)'	System	09 Aug 2020 21:23:21

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:01', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '0d35f32f-eecf-4649-a27c-69ed26d70bea'	System	09 Aug 2020 21:23:21
User entered 'No (N)'	System	09 Aug 2020 21:23:21

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:04', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '0d35f32f-eecf-4649-a27c-69ed26d70bea'	System	09 Aug 2020 21:23:21
User entered 'None (1)'	System	09 Aug 2020 21:23:21

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:16', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '0d35f32f-eecf-4649-a27c-69ed26d70bea'	System	09 Aug 2020 21:23:21
User entered '09 Aug 2020 16:23'	System	09 Aug 2020 21:23:21

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 5'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:20', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5ffa7157-032c-4f2e-b6ee-c136fe5486de'	System	10 Aug 2020 17:04:49
User entered 'None (1)'	System	10 Aug 2020 17:04:49

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:25', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5ffa7157-032c-4f2e-b6ee-c136fe5486de'	System	10 Aug 2020 17:04:49
User entered 'No (N)'	System	10 Aug 2020 17:04:49

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:28', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5ffa7157-032c-4f2e-b6ee-c136fe5486de'	System	10 Aug 2020 17:04:49
User entered 'No (N)'	System	10 Aug 2020 17:04:49

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:31', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5ffa7157-032c-4f2e-b6ee-c136fe5486de'	System	10 Aug 2020 17:04:49
User entered 'None (1)'	System	10 Aug 2020 17:04:49

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5ffa7157-032c-4f2e-b6ee-c136fe5486de' User entered '10 Aug 2020 12:04'	System	10 Aug 2020 17:04:49
	System	10 Aug 2020 17:04:49

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 6'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '73659868-d186-4255-afb9-101871a42b7c'	System	11 Aug 2020 17:16:09
User entered 'None (1)'	System	11 Aug 2020 17:16:09

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:38', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '73659868-d186-4255-afb9-101871a42b7c'	System	11 Aug 2020 17:16:09
User entered 'No (N)'	System	11 Aug 2020 17:16:09

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '73659868-d186-4255-afb9-101871a42b7c'	System	11 Aug 2020 17:16:09
User entered 'No (N)'	System	11 Aug 2020 17:16:09

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:15:51', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '73659868-d186-4255-afb9-101871a42b7c'	System	11 Aug 2020 17:16:09
User entered 'None (1)'	System	11 Aug 2020 17:16:09

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:16:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '73659868-d186-4255-afb9-101871a42b7c'	System	11 Aug 2020 17:16:09
User entered '11 Aug 2020 12:16'	System	11 Aug 2020 17:16:09

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 7'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:27', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b80db6b2-c39e-4dbe-87ba-a984a594941c'	System	12 Aug 2020 18:07:58
User entered 'None (1)'	System	12 Aug 2020 18:07:58

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:32', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b80db6b2-c39e-4dbe-87ba-a984a594941c'	System	12 Aug 2020 18:07:58
User entered 'No (N)'	System	12 Aug 2020 18:07:58

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:36', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b80db6b2-c39e-4dbe-87ba-a984a594941c'	System	12 Aug 2020 18:07:58
User entered 'No (N)'	System	12 Aug 2020 18:07:58

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b80db6b2-c39e-4dbe-87ba-a984a594941c'	System	12 Aug 2020 18:07:58
User entered 'None (1)'	System	12 Aug 2020 18:07:58

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:07:54', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b80db6b2-c39e-4dbe-87ba-a984a594941c'	System	12 Aug 2020 18:07:58
User entered '12 Aug 2020 13:07'	System	12 Aug 2020 18:07:58

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:50', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'None (0)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:40:56', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'None (0)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:41:00', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'None (0)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:41:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'None (0)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:41:09', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'None (0)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:41:13', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'None (0)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:41:19', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db'	System	06 Aug 2020 23:41:29
User entered 'No (N)'	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-06T18:41:27', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '09fbfc80-b7ee-499b-bcc1-a0e64ff6e6db' User entered '06 Aug 2020 18:41'	System	06 Aug 2020 23:41:29
	System	06 Aug 2020 23:41:29

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 18:17'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 20:47'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 21:42'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 2'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:22', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'None (0)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'None (0)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:37', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:45', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'None (0)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:54', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'None (0)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:25:58', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'None (0)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:26:08', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered 'No (N)'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-07T17:26:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ff23962a-813e-4b3a-b515-8f1c99e5dd37'	System	07 Aug 2020 22:26:33
User entered '07 Aug 2020 17:26'	System	07 Aug 2020 22:26:33

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 3'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:05', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'None (0)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:13', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'None (0)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:18', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'None (0)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:22', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'None (0)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'None (0)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:34', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'None (0)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:39', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered 'No (N)'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-08T12:05:54', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f0799bf9-12df-4097-97da-d17c9e60af6e'	System	08 Aug 2020 17:06:01
User entered '08 Aug 2020 12:05'	System	08 Aug 2020 17:06:01

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 4'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:28', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'None (0)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:32', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'None (0)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:37', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'None (0)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:40', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'None (0)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'None (0)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:46', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'None (0)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:23:51', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered 'No (N)'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-09T16:24:01', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '5fedb7a8-dbd3-484a-b427-43b17606796e'	System	09 Aug 2020 21:24:08
User entered '09 Aug 2020 16:24'	System	09 Aug 2020 21:24:08

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 5'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:52', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'None (0)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:04:59', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'None (0)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:05:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'None (0)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:05:13', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'None (0)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:05:22', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'None (0)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:05:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'None (0)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:05:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered 'No (N)'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-10T12:05:44', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b4c95e4d-7cda-4d68-afff-f221cb4ee94d'	System	10 Aug 2020 17:05:48
User entered '10 Aug 2020 12:05'	System	10 Aug 2020 17:05:48

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 6'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:16:22', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'None (0)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:16:32', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'None (0)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:16:42', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'None (0)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:16:49', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'None (0)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:16:57', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'None (0)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:17:10', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'None (0)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:17:19', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered 'No (N)'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-11T12:17:31', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'd7497fc7-aa97-4750-a404-55f1b3077bd1'	System	11 Aug 2020 17:17:35
User entered '11 Aug 2020 12:17'	System	11 Aug 2020 17:17:35

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 7'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:02', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:12', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:19', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:25', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:28', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered 'No (N)'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-08-12T13:08:46', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '2a768986-c574-42a4-9abc-008add484e5f'	System	12 Aug 2020 18:08:52
User entered '12 Aug 2020 13:08'	System	12 Aug 2020 18:08:52

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

US3272070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

US3272070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:00:04

US3272070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:00:04

US3272070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 20:00:04

US3272070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:00:04

US3272070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:00:09

US3272070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 20:00:09

US3272070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:00:23

US3272070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:21
User entered '20 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:00:23

US3272070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 20:00:23

US3272070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:21
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:00:23

US3272070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:00:28

US3272070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 20:00:28

US3272070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:00:40

US3272070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:33
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:00:40

US3272070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 20:00:40

US3272070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:33
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:00:40

US3272070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:00:47

US3272070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 20:00:47

US3272070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:38:59

US3272070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
Query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:40:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:47
User opened query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:48:48
User entered '3 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:41:44
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:38:59

US3272070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 21:38:59

US3272070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	04 Sep 2020 21:38:59

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:41:44
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:41:28
User entered '3 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:41:28
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:41:28
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:40:09
User entered '13:56'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 13:56'	System	04 Sep 2020 21:41:28
User entered '4 Sep 2020 13:56'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '36.7' C	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '105'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '18'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '137'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '76'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:41:44
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:41:28
User entered '3 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:41:28
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '15:25'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 15:25'	System	04 Sep 2020 21:41:28
User entered '4 Sep 2020 15:25'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '36.8' C	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '100'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '14'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '118'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '70'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:40:09

US3272070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:42:00

US3272070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:40:18
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:56
User opened query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:49:09
User entered '3 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:42:00

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:40:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User opened query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:48:59
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 21:41:44
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 21:41:44
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:38:59
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered '14:52'	(b) (4), (b) (6)	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 14:52'	System	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered 'ONCE'	System	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:57:19

US3272070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:42:17

US3272070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:19
User entered '3 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:42:17

US3272070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:19
User entered '14:19'	(b) (4), (b) (6)	04 Sep 2020 21:42:17

US3272070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 14:19'	System	04 Sep 2020 21:42:17

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered '14:05'	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 14:05'	System	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:42:30

US3272070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
Query 'Per CDM: Please complete Visit 3 forms.' answered with 'subject is deceased' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 20:02:11
	(b) (4), (b) (6)	29 Oct 2020 20:01:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:01:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:28
User opened query 'Per CDM: Please complete Visit 3 forms.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:49:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:42:34

US3272070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 20:01:52
User entered '1'	System	04 Sep 2020 21:42:34

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:25:51', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '246769b0-ed16-427f-b389-45e9c8350a25'	System	03 Sep 2020 20:26:54
User entered 'Yes (Y)'	System	03 Sep 2020 20:26:54

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:25:58', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '246769b0-ed16-427f-b389-45e9c8350a25'	System	03 Sep 2020 20:26:54
User entered '98.3'	System	03 Sep 2020 20:26:54

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:26:08', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '246769b0-ed16-427f-b389-45e9c8350a25'	System	03 Sep 2020 20:26:54
User entered 'No (N)'	System	03 Sep 2020 20:26:54

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:26:23', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '246769b0-ed16-427f-b389-45e9c8350a25'	System	03 Sep 2020 20:26:54
User entered '03 Sep 2020 15:26'	System	03 Sep 2020 20:26:54

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 15:12'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 2'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 3'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:13:45', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c992882e-b839-426a-a1a6-1223e3c4199d'	System	05 Sep 2020 17:14:15
User entered 'Yes (Y)'	System	05 Sep 2020 17:14:15

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:13:55', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c992882e-b839-426a-a1a6-1223e3c4199d'	System	05 Sep 2020 17:14:15
User entered '94.9'	System	05 Sep 2020 17:14:15

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:14:00', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c992882e-b839-426a-a1a6-1223e3c4199d'	System	05 Sep 2020 17:14:15
User entered 'No (N)'	System	05 Sep 2020 17:14:15

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:14:12', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'c992882e-b839-426a-a1a6-1223e3c4199d'	System	05 Sep 2020 17:14:15
User entered '05 Sep 2020 12:14'	System	05 Sep 2020 17:14:15

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 4'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:42:26', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'be347ae9-ffd9-44c8-9c00-decd6dd50665'	System	06 Sep 2020 21:42:56
User entered 'Yes (Y)'	System	06 Sep 2020 21:42:56

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:42:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'be347ae9-ffd9-44c8-9c00-decd6dd50665'	System	06 Sep 2020 21:42:56
User entered '94.9'	System	06 Sep 2020 21:42:56

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:42:39', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'be347ae9-ffd9-44c8-9c00-decd6dd50665'	System	06 Sep 2020 21:42:56
User entered 'No (N)'	System	06 Sep 2020 21:42:56

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:42:54', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'be347ae9-ffd9-44c8-9c00-decd6dd50665'	System	06 Sep 2020 21:42:56
User entered '06 Sep 2020 16:42'	System	06 Sep 2020 21:42:56

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 5'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:01', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '341b6daa-2b13-458a-894a-31ddf2f7dc14'	System	07 Sep 2020 17:05:32
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:32

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:14', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '341b6daa-2b13-458a-894a-31ddf2f7dc14'	System	07 Sep 2020 17:05:32
User entered '97.8'	System	07 Sep 2020 17:05:32

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:20', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '341b6daa-2b13-458a-894a-31ddf2f7dc14'	System	07 Sep 2020 17:05:32
User entered 'No (N)'	System	07 Sep 2020 17:05:32

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '341b6daa-2b13-458a-894a-31ddf2f7dc14'	System	07 Sep 2020 17:05:32
User entered '07 Sep 2020 12:05'	System	07 Sep 2020 17:05:32

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 6'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:02:17', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'e9c6221d-c4e2-41cc-bae9-440782477556'	System	08 Sep 2020 17:04:16
User entered 'Yes (Y)'	System	08 Sep 2020 17:04:16

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:02:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'e9c6221d-c4e2-41cc-bae9-440782477556'	System	08 Sep 2020 17:04:16
User entered '94.9'	System	08 Sep 2020 17:04:16

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:02:37', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'e9c6221d-c4e2-41cc-bae9-440782477556'	System	08 Sep 2020 17:04:16
User entered 'No (N)'	System	08 Sep 2020 17:04:16

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:02:50', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'e9c6221d-c4e2-41cc-bae9-440782477556'	System	08 Sep 2020 17:04:16
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 17:04:16

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 7'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:13', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f1bf9d87-293e-435d-b730-7fc2dbe0dfc3'	System	09 Sep 2020 19:16:38
User entered 'Yes (Y)'	System	09 Sep 2020 19:16:38

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:20', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f1bf9d87-293e-435d-b730-7fc2dbe0dfc3'	System	09 Sep 2020 19:16:38
User entered '97.9'	System	09 Sep 2020 19:16:38

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:26', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f1bf9d87-293e-435d-b730-7fc2dbe0dfc3'	System	09 Sep 2020 19:16:38
User entered 'No (N)'	System	09 Sep 2020 19:16:38

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f1bf9d87-293e-435d-b730-7fc2dbe0dfc3'	System	09 Sep 2020 19:16:38
User entered '09 Sep 2020 14:16'	System	09 Sep 2020 19:16:38

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:12', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '174155e8-bc80-4af6-b674-032bb4fe030e'	System	03 Sep 2020 20:30:47
User entered 'None (1)'	System	03 Sep 2020 20:30:47

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:16', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '174155e8-bc80-4af6-b674-032bb4fe030e'	System	03 Sep 2020 20:30:47
User entered 'No (N)'	System	03 Sep 2020 20:30:47

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:21', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '174155e8-bc80-4af6-b674-032bb4fe030e'	System	03 Sep 2020 20:30:47
User entered 'No (N)'	System	03 Sep 2020 20:30:47

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:27', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '174155e8-bc80-4af6-b674-032bb4fe030e'	System	03 Sep 2020 20:30:47
User entered 'None (1)'	System	03 Sep 2020 20:30:47

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:41', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '174155e8-bc80-4af6-b674-032bb4fe030e'	System	03 Sep 2020 20:30:47
User entered '03 Sep 2020 15:30'	System	03 Sep 2020 20:30:47

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 15:12'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 2'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 3'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:15:01', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f7c80ca3-06f7-435d-bac5-11297f0413b8'	System	05 Sep 2020 17:15:38
User entered 'None (1)'	System	05 Sep 2020 17:15:38

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:15:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f7c80ca3-06f7-435d-bac5-11297f0413b8'	System	05 Sep 2020 17:15:38
User entered 'No (N)'	System	05 Sep 2020 17:15:38

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:15:10', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f7c80ca3-06f7-435d-bac5-11297f0413b8'	System	05 Sep 2020 17:15:38
User entered 'No (N)'	System	05 Sep 2020 17:15:38

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:15:19', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f7c80ca3-06f7-435d-bac5-11297f0413b8'	System	05 Sep 2020 17:15:38
User entered 'None (1)'	System	05 Sep 2020 17:15:38

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-05T12:15:35', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'f7c80ca3-06f7-435d-bac5-11297f0413b8'	System	05 Sep 2020 17:15:38
User entered '05 Sep 2020 12:15'	System	05 Sep 2020 17:15:38

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 4'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:03', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '75711fb8-f9c1-40f0-992d-cf8ac731d039'	System	06 Sep 2020 21:43:37
User entered 'None (1)'	System	06 Sep 2020 21:43:37

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:08', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '75711fb8-f9c1-40f0-992d-cf8ac731d039'	System	06 Sep 2020 21:43:37
User entered 'No (N)'	System	06 Sep 2020 21:43:37

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:18', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '75711fb8-f9c1-40f0-992d-cf8ac731d039'	System	06 Sep 2020 21:43:37
User entered 'No (N)'	System	06 Sep 2020 21:43:37

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:23', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '75711fb8-f9c1-40f0-992d-cf8ac731d039'	System	06 Sep 2020 21:43:37
User entered 'None (1)'	System	06 Sep 2020 21:43:37

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:32', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '75711fb8-f9c1-40f0-992d-cf8ac731d039'	System	06 Sep 2020 21:43:37
User entered '06 Sep 2020 16:43'	System	06 Sep 2020 21:43:37

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 5'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:38', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '354a4ddd-6878-462c-8548-c9283a6c1b2f'	System	07 Sep 2020 17:06:15
User entered 'None (1)'	System	07 Sep 2020 17:06:15

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '354a4ddd-6878-462c-8548-c9283a6c1b2f'	System	07 Sep 2020 17:06:15
User entered 'No (N)'	System	07 Sep 2020 17:06:15

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:05:47', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '354a4ddd-6878-462c-8548-c9283a6c1b2f'	System	07 Sep 2020 17:06:15
User entered 'No (N)'	System	07 Sep 2020 17:06:15

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:01', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '354a4ddd-6878-462c-8548-c9283a6c1b2f'	System	07 Sep 2020 17:06:15
User entered 'None (1)'	System	07 Sep 2020 17:06:15

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:12', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '354a4ddd-6878-462c-8548-c9283a6c1b2f' User entered '07 Sep 2020 12:06'	System	07 Sep 2020 17:06:15
	System	07 Sep 2020 17:06:15

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 6'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:02:58', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '241aa167-3cdb-4792-a654-5b3f66d38bc3'	System	08 Sep 2020 17:04:42
User entered 'None (1)'	System	08 Sep 2020 17:04:42

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:02', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '241aa167-3cdb-4792-a654-5b3f66d38bc3'	System	08 Sep 2020 17:04:42
User entered 'No (N)'	System	08 Sep 2020 17:04:42

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:06', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '241aa167-3cdb-4792-a654-5b3f66d38bc3'	System	08 Sep 2020 17:04:42
User entered 'No (N)'	System	08 Sep 2020 17:04:42

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:10', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '241aa167-3cdb-4792-a654-5b3f66d38bc3'	System	08 Sep 2020 17:04:42
User entered 'None (1)'	System	08 Sep 2020 17:04:42

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:21', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '241aa167-3cdb-4792-a654-5b3f66d38bc3'	System	08 Sep 2020 17:04:42
User entered '08 Sep 2020 12:03'	System	08 Sep 2020 17:04:42

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 7'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ade2f144-b3a3-4e81-b7ae-420de1e9989c'	System	09 Sep 2020 19:17:10
User entered 'None (1)'	System	09 Sep 2020 19:17:10

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:47', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ade2f144-b3a3-4e81-b7ae-420de1e9989c'	System	09 Sep 2020 19:17:10
User entered 'No (N)'	System	09 Sep 2020 19:17:10

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:51', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ade2f144-b3a3-4e81-b7ae-420de1e9989c'	System	09 Sep 2020 19:17:10
User entered 'No (N)'	System	09 Sep 2020 19:17:10

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:16:54', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ade2f144-b3a3-4e81-b7ae-420de1e9989c'	System	09 Sep 2020 19:17:10
User entered 'None (1)'	System	09 Sep 2020 19:17:10

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:07', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'ade2f144-b3a3-4e81-b7ae-420de1e9989c'	System	09 Sep 2020 19:17:10
User entered '09 Sep 2020 14:17'	System	09 Sep 2020 19:17:10

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:52', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'None (0)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:55', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'None (0)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:30:58', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'None (0)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:31:02', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'None (0)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:31:05', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'None (0)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:31:08', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'None (0)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:31:13', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered 'No (N)'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-03T15:31:26', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '1a1d7740-7f56-4c98-bce0-932a6aafb659'	System	03 Sep 2020 20:31:31
User entered '03 Sep 2020 15:31'	System	03 Sep 2020 20:31:31

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 15:12'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 2'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 3'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 4'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:46', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'None (0)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:52', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'None (0)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:43:58', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'None (0)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:44:05', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'None (0)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:44:11', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'None (0)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:44:16', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'None (0)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:44:21', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered 'No (N)'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-06T16:44:33', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: 'b359c4e4-55d1-4d84-b1d1-f981c3e11c12'	System	06 Sep 2020 21:44:37
User entered '06 Sep 2020 16:44'	System	06 Sep 2020 21:44:37

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 5'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:20', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'None (0)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:24', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'None (0)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:30', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'None (0)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:34', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'None (0)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:39', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'None (0)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:43', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'None (0)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:47', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered 'No (N)'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-07T12:06:59', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '8640efa6-1c42-42e8-ad6c-f133f24c1cf6'	System	07 Sep 2020 17:07:03
User entered '07 Sep 2020 12:06'	System	07 Sep 2020 17:07:03

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 6'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:29', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'None (0)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:39', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'None (0)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:44', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'None (0)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:49', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'None (0)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:03:56', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'None (0)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:04:00', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'None (0)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:04:05', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered 'No (N)'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-08T12:04:18', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '04ce6f08-f6fe-4628-bc31-f0295e618381'	System	08 Sep 2020 17:05:16
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 17:05:16

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 7'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:14', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'None (0)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:19', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'None (0)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:22', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'None (0)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:25', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'None (0)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:28', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'None (0)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:31', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'None (0)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:37', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered 'No (N)'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (61c7c1b78f55bf68)', Time: '2020-09-09T14:17:48', User OID: 'PatientReportedOutcome (US3272070)', ODM File OID: '9c7b59d6-e804-49b7-9aa8-3077b99ea4c5'	System	09 Sep 2020 19:17:51
User entered '09 Sep 2020 14:17'	System	09 Sep 2020 19:17:51

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

US3272070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

US3272070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:02:46

US3272070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:57
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:02:46

US3272070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 15:02:46

US3272070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:02:46

US3272070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:02:51

US3272070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 15:02:51

US3272070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:21:44

US3272070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:21:44

US3272070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 17:21:44

US3272070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:21:44

US3272070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:21:47

US3272070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 17:21:47

US3272070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:43:55

US3272070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:43:55

US3272070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 18:43:55

US3272070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:43:55

US3272070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:43:59

US3272070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 18:43:59

US3272070

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:50:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:18:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	02 Oct 2020 15:07:20
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:27:17

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:25
User entered 'USA-US070-2020-mRNA-1273-P301000003'	System	02 Oct 2020 16:54:22
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 16:54:22

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:11:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:11:59
Data point term sent to Coder	System	02 Oct 2020 15:11:17
User entered 'Myocardial Infarction'	Kayla Flege (b) (4) (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'Yes (Y)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'No (N)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'No (N)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '1 Oct 2020'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
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).	System	02 Oct 2020 15:11:06
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4)	02 Oct 2020 15:11:06
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	02 Oct 2020 15:10:42
User entered '10:00'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:11:06
User entered '1 Oct 2020 10:00'	System	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'No (N)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '1 Oct 2020'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'Grade 4 (Grade 4)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'Yes (Y)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:03
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Unknown if autopsy was performed.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:34:12
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:48:36
User entered 'I'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

US3272070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User closed query 'PV Query: As subject had already received both doses of study drug prior to event, please consider updating action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:12
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
Query 'PV Query: As subject had already received both doses of study drug prior to event, please consider updating action taken to not applicable.' answered with 'Unknown.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:35:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Adam Brosz (b) (4)	15 Oct 2020 17:34:41
User opened query 'PV Query: As subject had already received both doses of study drug prior to event, please consider updating action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:49:55
User entered 'None (NONE)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'I'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered '0'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered 'Fatal (FATAL)'	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the course of the event in the hospital. Was the subject hospitalized overnight for the event?' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 02:50:35
User closed query 'PV Query: It was reported that the chest x-ray was performed. Please provide the chest x-ray results when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 02:50:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 02:50:30
User closed query 'PV Query: Please provide results of cardiology notes and death certificate when available or as applicable with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 02:50:29
Query 'PV Query: Please provide the course of the event in the hospital. Was the subject hospitalized overnight for the event?' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:05:40
Query 'PV Query: It was reported that the chest x-ray was performed. Please provide the chest x-ray results when available.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:05:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc). Please leave query open until information is received.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:05:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide results of cardiology notes and death certificate when available or as applicable with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'UPDATED' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:18
User opened query 'PV Query: Please provide the course of the event in the hospital. Was the subject hospitalized overnight for the event?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:59:11
User opened query 'PV Query: It was reported that the chest x-ray was performed. Please provide the chest x-ray results when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:36:59
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:36:51
User closed query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:36:38
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:43:09
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:43:05
	(b) (4), (b) (6)	06 Nov 2020 14:43:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' answered with 'PT PRESENTED VIA EMS AS A CARDIAC ARREST ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 21:49:36
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' answered with 'TRATEMENTS AND MEDS ON HISTORY AND CON MED PAGE' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 21:46:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc). Please leave query open until information is received.' answered with 'CHEST X-RAY DONE ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 21:46:27
User opened query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:59:46
User opened query 'PV Query: Please provide results of cardiology notes and death certificate when available or as applicable with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:59:33
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:59:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:59:19
User closed query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:39
User closed query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:36
User closed query 'PV Query: Please provide results of cardiology notes and death certificate when available or as applicable with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:34
User closed query 'PV Query: Please provide any relevant medical history including history of similar episodes with onset date(s), severity, treatment and relevant details.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:30
User closed query 'PV Query: Please indicate any risk factors the subject had for the development of the event (dyslipidemia, coronary artery disease, previous myocardial infarction, cardiomyopathy, valvular heart disease, atrial fibrillation/dysrhythmia, prior CHF, smoking, alcohol, etc).' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:27
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc).' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:22
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:13:19
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:35:13
Query 'PV Query: Please report if there were any factors that precipitated the event.' answered with 'Unknown. Elderly male with numerous cardiovascular risk factors.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:33:45
Query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' answered with 'Unknown at this time pending hospitalization documentation.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:33:13
Query 'PV Query: Please provide results of cardiology notes and death certificate when available or as applicable with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Unknown at this time. Pending results.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:32:51
Query 'PV Query: Please provide any relevant medical history including history of similar episodes with onset date(s), severity, treatment and relevant details.' answered with 'Diabetes mellitus, hypertension, hyperlipidemia.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:32:34
Query 'PV Query: Please indicate any risk factors the subject had for the development of the event (dyslipidemia, coronary artery disease, previous myocardial infarction, cardiomyopathy, valvular heart disease, atrial fibrillation/dysrhythmia, prior CHF, smoking, alcohol, etc).' answered with 'Diabetes mellitus, hypertension, hyperlipidemia.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Unknown at this time, pending results.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:31:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc).' answered with 'Unknown at this time, pending results.' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:31:43
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Myocardial infarction' (Site from Safety).	Adam Brosz (b) (4)	15 Oct 2020 17:31:29
User opened query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:49:40
User opened query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:49:33
User opened query 'PV Query: Please provide results of cardiology notes and death certificate when available or as applicable with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:49:25
User opened query 'PV Query: Please provide any relevant medical history including history of similar episodes with onset date(s), severity, treatment and relevant details.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:49:17
User opened query 'PV Query: Please indicate any risk factors the subject had for the development of the event (dyslipidemia, coronary artery disease, previous myocardial infarction, cardiomyopathy, valvular heart disease, atrial fibrillation/dysrhythmia, prior CHF, smoking, alcohol, etc).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:49:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:48:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable (i.e. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:48:47
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:47:55
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Oct 2020 15:11:45
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Oct 2020 15:11:45
User entered 'Subject had myocardial infarction that resulted in death.' reason for change: Data Entry Error	Kayla Flege (b) (4)	02 Oct 2020 15:11:45
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Oct 2020 15:10:42
User entered empty.	Kayla Flege (b) (4)	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 15:10:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 15:10:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:59:24
User closed query 'Per source additional conmeds were given including: Rocuronium, Ketamine, Propofol, PR aspirin, Calcium and oxygen. Consider adding.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:06
Query 'Per source additional conmeds were given including: Rocuronium, Ketamine, Propofol, PR aspirin, Calcium and oxygen. Consider adding.' answered with 'updated Con meds accordingly ' (Site from CRA).	Ashley Bell (b) (4)	21 Oct 2020 02:24:00
User opened query 'Per source additional conmeds were given including: Rocuronium, Ketamine, Propofol, PR aspirin, Calcium and oxygen. Consider adding.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 17:03:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:01:19

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 23:39:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 23:39:05
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	20 Nov 2020 19:33:05 20 Nov 2020 19:32:27
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:57:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:57:11
Data point term sent to Coder Coding entries removed.	System Kayla Flege (b) (4) (b) (4)	27 Oct 2020 15:52:51 27 Oct 2020 15:52:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:43:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:43:51
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Sep 2020 22:35:23 21 Sep 2020 22:34:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:16:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:16:45
Data point term sent to Coder	System	28 Aug 2020 20:04:13
User entered 'amitriptyline'	(b) (4), (b) (6) (b) (4)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
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 'Indication is diabetic neuropathy ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 19:32:52
User entered 'Diabetic Neuropathy.' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 19:32:27
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). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:32:27
Query 'Per MM: Please clarify indication.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	27 Oct 2020 15:52:14
	(b) (4)	
User entered 'Type 2 diabetes mellitus' reason for change: Data Entry Error	Kayla Flege (b) (4)	27 Oct 2020 15:52:08
	(b) (4)	
User opened query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:40:42
User closed query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:40:14
Query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please update indication as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:35:00
User entered 'DIABETES mellitus type 2' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 22:34:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:17:11
User entered 'diabetes'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '75'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:03:44

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:05:42
Data point term sent to Coder	System	28 Aug 2020 20:05:17
User entered 'cholecalciferol'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '50'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:04:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:06:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:06:44
Data point term sent to Coder	System	28 Aug 2020 20:06:21
User entered 'gabapentin'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment or prophylaxis for the indicated condition. Please update indication to reflect Prophylaxis and include the medical condition that the medication used to prevent. Please update applicable details or provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:37:24
Query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment or prophylaxis for the indicated condition. Please update indication to reflect Prophylaxis and include the medical condition that the medication used to prevent. Please update applicable details or provide clarification. ' answered with 'per patient medication is used for this indication' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:35:36
User opened query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment or prophylaxis for the indicated condition. Please update indication to reflect Prophylaxis and include the medical condition that the medication used to prevent. Please update applicable details or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:18:29
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '300'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2008'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:05:53

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 08:09:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 08:09:33
Data point term sent to Coder	System	28 Aug 2020 20:07:23
User entered 'insulin 500 (pen)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update the dose as appropriate or comment to confirm that daily dose is 100 iu. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:13:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
Query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update the dose as appropriate or comment to confirm that daily dose is 100 iu. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:36:39
User opened query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update the dose as appropriate or comment to confirm that daily dose is 100 iu. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:19:09
User entered '100'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 22:36:31
User entered 'IU (IU)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'units' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 22:36:31
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2000'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:06:59

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:45:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:45:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Sep 2020 22:44:34 21 Sep 2020 22:44:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:47:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:47:49
Data point term sent to Coder User entered 'losartan'	System (b) (4), (b) (6)	28 Aug 2020 20:08:26 28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please update indication as appropriate or provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:37:51
User entered 'hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 19:15:41
Query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please update indication as appropriate or provide clarification.' answered with 'per patient used for this indication' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:44:14
User opened query 'Per DM CLR: Please review Indication and please note that this medication is not typically used as treatment for the indicated condition. Please update indication as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:37:05
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	17 Sep 2020 05:19:57
		28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update the dose as appropriate or provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 11:14:14
Query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update the dose as appropriate or provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:44:43
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 22:44:14
User opened query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update the dose as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:20:12
User entered '1000'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2018'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:08:21

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 20:11:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 20:11:42
Data point term sent to Coder	System	28 Aug 2020 20:10:28
User entered 'metformin'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 1987'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:09:34

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:12:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:12:46
Data point term sent to Coder	System	28 Aug 2020 20:12:31
User entered 'simvastatin'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '20'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:12:05

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:15:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:15:50
Data point term sent to Coder	System	28 Aug 2020 20:14:39
User entered 'cyanocobalamin'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'nutritional supplement'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:18:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
Query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:40:51
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 22:40:44
User opened query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:17:42
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 22:40:44
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:14:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 06:16:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 06:16:29
Data point term sent to Coder	System	28 Aug 2020 20:15:42
User entered 'empagliflozin'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '25'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2019'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:15:31

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:17:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:17:40
Data point term sent to Coder	System	28 Aug 2020 20:16:45
User entered 'hydrochlorothiazide'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'hypertension'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '25'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2017'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:16:36

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
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)	28 Aug 2020 20:18:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:18:42
Data point term sent to Coder	System	28 Aug 2020 20:17:48
User entered 'aspirin'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'cardiac prophylaxis'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '21'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 1987'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 20:17:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
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)	21 Oct 2020 09:39:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:39:57
Data point term sent to Coder	System	21 Oct 2020 02:25:00
User entered 'ASPIRIN'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '300'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Rectal (RECTAL)'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:17:24
	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:28:46
	(b) (4), (b) (6)	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:24:18

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:52:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:52:26
Data point term sent to Coder	System	21 Oct 2020 02:29:00
User entered 'PROPOFOL'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'TITRATION DRIP'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:16:23
	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:28:58
	(b) (4), (b) (6)	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:28:15

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: PHENYLALKYLAMINE DERIVATIVES, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:41:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:41:30
Data point term sent to Coder	System	21 Oct 2020 02:30:01
User entered 'VERAPAMIL'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '2.5'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'INTRA ARTERIAL'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:18:02
	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:29:10
	(b) (4), (b) (6)	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:29:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:00:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:00:32
Data point term sent to Coder	System	21 Oct 2020 02:32:01
User entered 'NITROGLYCERIN'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '200'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MCG'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'INTRA ARTERIAL'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:29:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:31:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:46:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:46:25
Data point term sent to Coder	System	21 Oct 2020 02:33:02
User entered 'SODIUM CHLORIDE 0.9%'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '999'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mL (mL)'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:18:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:32:04

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:43:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:43:31
Data point term sent to Coder	System	21 Oct 2020 02:34:02
User entered 'HEPARIN'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mL (mL)'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'INTRA ARTERIAL'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:19:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 02:51:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 02:51:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 02:51:25
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 02:33:13
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:55:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:55:27
Data point term sent to Coder	System	21 Oct 2020 02:35:02
User entered 'PHENYLEPHRINE'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MCG'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:19:29
	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:30:14
	(b) (4), (b) (6)	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:34:08

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:33:33
Data point term sent to Coder	System	21 Oct 2020 02:36:03
User entered 'EPINEPHRINE'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:19:52
	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:30:25
	(b) (4), (b) (6)	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:35:09

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:12:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:12:31
Data point term sent to Coder	System	21 Oct 2020 02:37:03
User entered 'IOPAMIDOL'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '95'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mL (mL)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:20:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:30:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:36:40

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:00:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:00:31
Data point term sent to Coder	System	21 Oct 2020 02:40:05
User entered 'NOEPINEPHRINE'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '30'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MCG'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'TITRATION DRIP'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:20:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:30:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:39:16

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: VASOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:41:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:41:31
Data point term sent to Coder	System	21 Oct 2020 02:43:06
User entered 'VASOPRESSIN'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '.04'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'IU (IU)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'Confirmed correct, pt died of myocardial infarction. Records sent. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:21:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:31:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:50:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 02:42:26

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:50:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:00
User closed query 'Subject have a right femoral central line placed and a right radial arterial line place. Consider adding. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 18:59:55
User closed query 'Subject had concomitant procedures completed including, 1. Intubation with Mechanical ventilation 10/1 2. Cardiac catheterization Consider adding to the CRF. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 18:59:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 02:44:14
Query 'Subject have a right femoral central line placed and a right radial arterial line place. Consider adding. ' answered with 'updated accordingly ' (Site from CRA).	Ashley Bell (b) (4)	21 Oct 2020 02:24:33
Query 'Subject had concomitant procedures completed including, 1. Intubation with Mechanical ventilation 10/1 2. Cardiac catheterization Consider adding to the CRF. ' answered with 'updated accordingly ' (Site from CRA).	Ashley Bell (b) (4)	21 Oct 2020 02:24:26
User opened query 'Subject have a right femoral central line placed and a right radial arterial line place. Consider adding. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 17:05:50
User opened query 'Subject had concomitant procedures completed including, 1. Intubation with Mechanical ventilation 10/1 2. Cardiac catheterization Consider adding to the CRF. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:45:12
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:27:04

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:50:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:44:59

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:50:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'INTUBATION'	(b) (4), (b) (6)	21 Oct 2020 02:44:59

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Oct 2020 02:44:59

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:50:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:44:59

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:50:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:45:17

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:50:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'MECHANICAL VENTILATON'	(b) (4), (b) (6)	21 Oct 2020 02:45:17

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Oct 2020 02:45:17

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:50:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:45:17

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:45:41

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'ARTERIAL LINE INSERTION'	(b) (4), (b) (6)	21 Oct 2020 02:45:41

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Oct 2020 02:45:41

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:45:41

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 10:50:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:46:02

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 10:50:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'CENTRAL VENOUS CATHETER INSERTION'	(b) (4), (b) (6)	21 Oct 2020 02:46:02

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Oct 2020 02:46:02

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 10:50:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:46:02

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:50:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 02:46:26

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:50:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'CORONARY CATHETERIZATION'	(b) (4), (b) (6)	21 Oct 2020 02:46:26

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:50:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Oct 2020 02:46:26

US3272070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:50:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 02:46:26

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
DataPoint Un-verified.	Kayla Flege (b) (4)	21 Nov 2020 14:15:38
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Nov 2020 14:15:38
DataPoint Verified.	Kayla Flege (b) (4)	21 Nov 2020 14:15:38
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	12 Oct 2020 16:48:22
User entered '1 Oct 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	12 Oct 2020 16:48:22
	(b) (4)	
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	12 Oct 2020 16:47:56
User entered '12 Oct 2020'	Kayla Flege (b) (4)	12 Oct 2020 16:47:56
	(b) (4)	

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

[Reason for discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered 'Death (DEATH)'	Kayla Flege (b) (4) (b) (4)	12 Oct 2020 16:47:56

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	12 Oct 2020 16:47:56

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
User closed query 'Per CDM Re-Query: previous response noted; however, there is an event recorded as fatal, please select Adverse Event as cause of death is an AE/SAE' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:31:10
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	21 Nov 2020 14:15:56
Query 'Per CDM Re-Query: previous response noted; however, there is an event recorded as fatal, please select Adverse Event as cause of death is an AE/SAE' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:43
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	21 Nov 2020 14:15:30
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:30
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:30
User opened query 'Per CDM Re-Query: previous response noted; however, there is an event recorded as fatal, please select Adverse Event as cause of death is an AE/SAE' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:05:56
User closed query 'Per CDM: per sponsor review, please consider selecting 'Adverse event' and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:05:56
Query 'Per CDM: per sponsor review, please consider selecting 'Adverse event' and make all applicable updates.' answered with 'Information is correct.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:25:14
User opened query 'Per CDM: per sponsor review, please consider selecting 'Adverse event' and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:42:42
Query 'Per CDM: per sponsor review, Reason for Discontinuation is recorded as Death, however, AE record number should be recorded. Please update accordingly' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:41:53
User opened query 'Per CDM: per sponsor review, Reason for Discontinuation is recorded as Death, however, AE record number should be recorded. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:01:57

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered 'Other (OTHER)'	Kayla Flege (b) (4) (b) (4)	12 Oct 2020 16:47:56

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

If main cause of death is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
DataPoint Un-verified.	Kayla Flege (b) (4)	21 Nov 2020 14:15:56
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kayla Flege (b) (4)	21 Nov 2020 14:15:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered 'Myocardial Infarction'	Kayla Flege (b) (4)	12 Oct 2020 16:47:56
	(b) (4)	

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
DataPoint Un-verified.	Kayla Flege (b) (4)	21 Nov 2020 14:15:30
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Nov 2020 14:15:30
DataPoint Verified.	Kayla Flege (b) (4)	21 Nov 2020 14:15:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered '1 Oct 2020'	(b) (4), (b) (6)	
	Kayla Flege (b) (4)	12 Oct 2020 16:47:56
	(b) (4)	

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:34

[Was autopsy performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered 'Unknown (UNK)'	Kayla Flege (b) (4) (b) (4)	12 Oct 2020 16:47:56

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Adam'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '2444 W. Faidley Ave'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Grand Island'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'NE'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '68803'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:13:51
User entered 'US'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:50:54
User entered '3'	System	06 Nov 2020 14:43:33
User entered '2'	System	16 Oct 2020 13:13:59
User entered '1'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Adam'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '2444 W. Faidley Ave'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Grand Island'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'NE'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '68803'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:13:51
User entered 'US'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:50:54
User entered '3'	System	06 Nov 2020 14:43:33
User entered '2'	System	16 Oct 2020 13:13:59
User entered '1'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:50:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
User entered '02/Oct/2020 12:54'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:50:34

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:13:51
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Adam'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '2444 W. Faidley Ave'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Grand Island'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'NE'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '68803'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:13:51
User entered 'US'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:50:54
User entered '3'	System	06 Nov 2020 14:43:33
User entered '2'	System	16 Oct 2020 13:13:59
User entered '1'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:50:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
User entered '16/Oct/2020 13:13'	System	16 Oct 2020 13:13:59

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:50:34

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)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 14:43:22
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 13:13:59

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Adam'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '2444 W. Faidley Ave'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Grand Island'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'NE'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '68803'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:13:51
User entered 'US'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:50:54
User entered '3'	System	06 Nov 2020 14:43:33
User entered '2'	System	16 Oct 2020 13:13:59
User entered '1'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:50:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:00:43
User entered '06/Nov/2020 14:43'	System	06 Nov 2020 14:43:33

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:50:34

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)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 02:50:46
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:00:43
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 14:43:33

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Adam'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '2444 W. Faidley Ave'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'Grand Island'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered 'NE'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:54:43
User entered '68803'	System	02 Oct 2020 16:54:22

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:13:51
User entered 'US'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:50:54
User entered '3'	System	06 Nov 2020 14:43:33
User entered '2'	System	16 Oct 2020 13:13:59
User entered '1'	System	02 Oct 2020 16:54:50

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:50:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 21:50'	System	24 Nov 2020 02:50:54

US3272070

Folder: SAE USA-US070-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:50:34

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 02:50:54