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

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:24:07

All time stamps listed in this document are displayed in GMT

US3272070
Form: Participant Creation
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Participant ID	US3272070

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-1615541

US3272070
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-1615542

US3272070
Folder: Screening
Form: Demographics
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
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

FDA-CBER-2022-1614-1615543

US3272070
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615544

US3272070
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Did the participant meet all eligibility criteria? Yes ☒ No ☐

FDA-CBER-2022-1614-1615545

US3272070
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-1615546

US3272070
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
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)	

US3272070
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
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)	

FDA-CBER-2022-1614-1615548

US3272070
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
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)	

FDA-CBER-2022-1614-1615549

US3272070
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
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)	

FDA-CBER-2022-1614-1615550

US3272070
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	16:24 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:24
Height *(xxx.x)*	175 cm
Weight *(xxx.x)*	112.4 kg
BMI *(xxx.x)*	36.70204 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-1615551

US3272070
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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.

FDA-CBER-2022-1614-1615552

US3272070
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615553

US3272070
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Resides in Nursing Home or Assisted Living Facility	False
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	

US3272070
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-1615555

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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 ■

FDA-CBER-2022-1614-1615556

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-1615557

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
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 ☐ Axillary ☐ Other ■
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

FDA-CBER-2022-1614-1615558

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
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 ☐ Axillary ☐ Other ■
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

FDA-CBER-2022-1614-1615559

US3272070
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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.

FDA-CBER-2022-1614-1615560

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	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 ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-1615561

US3272070
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	6 AUG 2020
Collection time *(00:00-23:59)*	17:04 (24 HR)
Collection date and time (derived)	6 AUG 2020 17:04

FDA-CBER-2022-1614-1615562

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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		

FDA-CBER-2022-1614-1615563

US3272070
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615564

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07

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

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

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07

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

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07

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

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07

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

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07

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

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

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	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: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 2
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	07 AUG 2020 17:25
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-1615575

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 AUG 2020 12:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-1615576

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 4
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	09 AUG 2020 16:23
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-1615577

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 5
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	10 AUG 2020 12:04
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-1615578

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 AUG 2020 12:16
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-1615579

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	12 AUG 2020 13:07
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-1615580

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: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615582

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: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615584

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07

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 ■

FDA-CBER-2022-1614-1615585

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07

	Yes
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

FDA-CBER-2022-1614-1615586

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

	Yes ☐
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

FDA-CBER-2022-1614-1615588

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: 09 Jun 2021 16:24:07

	Yes
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

FDA-CBER-2022-1614-1615590

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: 09 Jun 2021 16:24:07

	Yes ☐
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

FDA-CBER-2022-1614-1615592

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: 09 Jun 2021 16:24:07

	Yes ☐
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

FDA-CBER-2022-1614-1615594

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: 09 Jun 2021 16:24:07

	Yes
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

FDA-CBER-2022-1614-1615596

US3272070
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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	

FDA-CBER-2022-1614-1615597

US3272070
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615598

US3272070
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615600

US3272070
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615602

US3272070
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-1615603

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
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 ■ Axillary ☐ Other ☐
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

FDA-CBER-2022-1614-1615604

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
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 ■ Axillary ☐ Other ☐
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

FDA-CBER-2022-1614-1615605

US3272070
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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.

FDA-CBER-2022-1614-1615606

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	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 ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-1615607

US3272070
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	3 SEP 2020
Collection time *(00:00-23:59)*	14:19 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:19

FDA-CBER-2022-1614-1615608

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615609

US3272070
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ☐ No ■
Continuing Flag	

FDA-CBER-2022-1614-1615610

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07

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

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

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: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

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

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: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

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: 09 Jun 2021 16:24:07

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	03 SEP 2020 15:30
PC Open Date & Time	03 SEP 2020 15:12
PC Close Date & Time	03 SEP 2020 17:42

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: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 2
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	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-1615621

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 3
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	05 SEP 2020 12:15
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-1615622

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 4
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 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: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 5
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	07 SEP 2020 12:06
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-1615624

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 SEP 2020 12:03
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-1615625

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07

TIMEPOINT	DAY 7
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	09 SEP 2020 14:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

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: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615628

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: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615630

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: 09 Jun 2021 16:24:07

	Yes ☐
PC Time stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-1615632

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 ☐

	Yes ☐
PC Time stamp	
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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: 09 Jun 2021 16:24:07

	Yes
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

FDA-CBER-2022-1614-1615636

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07

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 ■

FDA-CBER-2022-1614-1615637

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07

	Yes
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: 09 Jun 2021 16:24:07

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 ■

FDA-CBER-2022-1614-1615639

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07

	Yes
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

FDA-CBER-2022-1614-1615640

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: 09 Jun 2021 16:24:07

	Yes ☐
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

FDA-CBER-2022-1614-1615642

US3272070
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615643

US3272070
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615644

US3272070
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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	

FDA-CBER-2022-1614-1615645

US3272070
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615646

US3272070
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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*	

FDA-CBER-2022-1614-1615647

US3272070
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1615648

US3272070
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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	_____

FDA-CBER-2022-1614-1615649

US3272070
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615650

US3272070
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

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.

FDA-CBER-2022-1614-1615651

US3272070
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

FDA-CBER-2022-1614-1615652

US3272070
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

FDA-CBER-2022-1614-1615653

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

US3272070
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

FDA-CBER-2022-1614-1615655

US3272070
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-1615656

US3272070
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

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	_____

FDA-CBER-2022-1614-1615657

US3272070
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	
Was the participant unblinded?	Yes ☐ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☐
Date of unblinding *(dd MMM yyyy)*	
Participant randomization assignment	mRNA-1273 ☐ Placebo ☐
Actual Dose 1	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-1615658

US3272070
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

FDA-CBER-2022-1614-1615659

US3272070
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00 - 23:59)*	
Collection Date and Time (derived)	

US3272070
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Did the participant experience any adverse events? Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-1615661

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

AEID	USA-US070-2020-MRNA-1273-P30 1000003
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	1 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	1 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	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 ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ■ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 Ony)	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
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-1615664

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	AMITRIPTYLINE
Prophylaxis	Yes ☐ No ■
Indication	TYPE 2 DIABETES MELLITUS
Dose per administration	75
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	CHOLECALCIFEROL
Prophylaxis	Yes ☐ No ■
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	50
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-1615667

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1987
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ○ No ●
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	20
Dose unit	mg ● ug ○ mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ● twice daily ○ three times daily ○ four times daily ○ every other day ○ every week ○ every month ○ as needed ○ once ○ unknown ○ other ○
If frequency is Other, specify	
Route of administration	Oral ● Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	CARDIAC PROPHYLAXIS
Dose per administration	21
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1987
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ■
Indication	MYOCARDIAL INFARCTION
Dose per administration	300
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ■
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	VERAPAMIL
Prophylaxis	Yes ○ No ●
Indication	MYOCARDIAL INFARCTION
Dose per administration	2.5
Dose unit	mg ● ug ○ mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ○ twice daily ○ three times daily ○ four times daily ○ every other day ○ every week ○ every month ○ as needed ○ once ● unknown ○ other ○
If frequency is Other, specify	
Route of administration	Oral ○ Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○

FDA-CBER-2022-1614-1615691

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ■
If route of administration is Other, specify	INTRA ARTERIAL
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ■
If route of administration is Other, specify	INTRA ARTERIAL
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

FDA-CBER-2022-1614-1615695

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

Name of Medication	HEPARIN
Prophylaxis	Yes No ■
Indication	MYOCARDIAL INFARCTION
Dose per administration	100
Dose unit	mg ug mL g IU tablet capsule puff Other ■
If dose unit is Other, specify	UNITS
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once ■ unknown other
If frequency is Other, specify	
Route of administration	Oral Topical Subcutaneous Transdermal Intraocular

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ■
If route of administration is Other, specify	INTRA ARTERIAL
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Data signed: (b) (4) **14 Mar 2021 17:23:18**
Generated On: 09 Jun 2021 16:24:07

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Were any concomitant procedures performed? Yes ☒ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-1615709

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
01 OCT 2020	INTUBATION	Adverse Event	
01 OCT 2020	MECHANICAL VENTILATON	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	

US3272070
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **14 Mar 2021 17:23:19**
Generated On: 09 Jun 2021 16:24:07

Date of study discontinuation/completion *(dd MMM yyyy)*	01 OCT 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ■ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ■ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	01 OCT 2020
Was autopsy performed?	Yes ☐ No ☐ Unknown ■

FDA-CBER-2022-1614-1615711

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	5

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	5
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)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	5
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)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	5
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)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	5
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

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Data signed: (b) (4) **14 Mar 2021 17:23:20**
Generated On: 09 Jun 2021 16:24:07

SAEID	USA-US070-2020-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	5
Date of submission (Pre-filled from custom function)	03/DEC/2020 15:40
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: 09 Jun 2021 16:24:07
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:08:25
User entered 'US3272070'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 22:14:18

US3272070
Form: Participant Creation
Generated On: 09 Jun 2021 16:24:07

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26

FDA-CBER-2022-1614-1615720

US3272070
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:46
User entered 'Yes (Y)'		28 Aug 2020 19:45:23

FDA-CBER-2022-1614-1615721

US3272070
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615722

US3272070
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615723

US3272070
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'SCRN'	System	28 Aug 2020 19:45:23

FDA-CBER-2022-1614-1615724

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615725

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615726

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'YEARS'	System	28 Aug 2020 19:46:26

FDA-CBER-2022-1614-1615727

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '74'	System	06 Aug 2020 23:13:05

FDA-CBER-2022-1614-1615728

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered 'Male (M)'		28 Aug 2020 19:46:26

FDA-CBER-2022-1614-1615729

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		28 Aug 2020 19:46:26

FDA-CBER-2022-1614-1615730

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '1'		28 Aug 2020 19:46:26

FDA-CBER-2022-1614-1615731

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:27
User entered '0'		28 Aug 2020 19:46:26

FDA-CBER-2022-1614-1615732

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615733

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615734

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615735

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615736

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615737

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615738

US3272070
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:24:07
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615739

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615740

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'Aug 2020'	System	06 Aug 2020 23:13:05

FDA-CBER-2022-1614-1615741

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2020'	System	06 Aug 2020 23:13:05

FDA-CBER-2022-1614-1615742

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615743

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615744

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615748

US3272070
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:24:07
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	06 Aug 2020 23:13:05

FDA-CBER-2022-1614-1615749

US3272070
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 16:24:07
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615750

US3272070
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:24:07
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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)'		28 Aug 2020 19:47:55

FDA-CBER-2022-1614-1615751

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615752

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615753

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615754

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615755

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615756

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615757

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'Jan 2000'	System	28 Aug 2020 19:48:24

FDA-CBER-2022-1614-1615758

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2000'	System	28 Aug 2020 19:48:24

FDA-CBER-2022-1614-1615759

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:48:24

FDA-CBER-2022-1614-1615760

US3272070
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:24:07
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:48:24

FDA-CBER-2022-1614-1615761

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:06:58
User coded data point as SOC: Vascular disorders, HLGT: 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

FDA-CBER-2022-1614-1615762

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615763

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615764

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615765

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615766

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615767

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'Jan 2017'	System	28 Aug 2020 19:49:49

FDA-CBER-2022-1614-1615768

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2017'	System	28 Aug 2020 19:49:49

FDA-CBER-2022-1614-1615769

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:49:49

FDA-CBER-2022-1614-1615770

US3272070
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:24:07
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:49:49

FDA-CBER-2022-1614-1615771

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615772

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615773

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615774

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615775

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615776

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615777

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'Jan 2010'	System	28 Aug 2020 19:50:08

FDA-CBER-2022-1614-1615778

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2010'	System	28 Aug 2020 19:50:08

FDA-CBER-2022-1614-1615779

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:50:08

FDA-CBER-2022-1614-1615780

US3272070
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:24:07
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:50:08

FDA-CBER-2022-1614-1615781

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:19:29
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no meds taken' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 16:44:00
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 21:05:27
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: 09 Jun 2021 16:24:07
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615783

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615784

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615785

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615786

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615787

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'Jan 2020'	System	21 Oct 2020 00:54:02

FDA-CBER-2022-1614-1615788

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2020'	System	21 Oct 2020 00:54:02

FDA-CBER-2022-1614-1615789

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 00:54:02

FDA-CBER-2022-1614-1615790

US3272070
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:24:07
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 00:54:02

FDA-CBER-2022-1614-1615791

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615792

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615793

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615794

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615795

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615798

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615799

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615800

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Temperature *(xxx.x)*

Audit	User	Time (GMT)
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

FDA-CBER-2022-1614-1615801

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615803

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615804

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615805

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615806

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615807

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615808

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615809

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615810

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1615811

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26

FDA-CBER-2022-1614-1615812

US3272070
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:24:07
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26

FDA-CBER-2022-1614-1615813

US3272070
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:24:07
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615814

US3272070
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:24:07
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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 is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:38:59
User entered '6 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:52:41

FDA-CBER-2022-1614-1615815

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615818

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615819

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615820

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615824

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615827

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615828

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

FDA-CBER-2022-1614-1615829

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615830

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:07:15
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 19:55:18

FDA-CBER-2022-1614-1615835

US3272070
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:24:07
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615836

US3272070
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615837

US3272070
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per CDM: Please update date in correct format (dd MMM yyyy). Thanks' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:46:06
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: 09 Jun 2021 16:24:07
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615839

US3272070
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'VISIT1'	System	28 Aug 2020 19:55:32

FDA-CBER-2022-1614-1615840

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615841

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615842

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615843

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615844

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615845

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615846

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615847

US3272070
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:24:07
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615848

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:24:07
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615849

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:24:07
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615850

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:24:07
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615851

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:24:07
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615852

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615853

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615854

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615855

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615856

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '6 Aug 2020 16:24'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615857

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615858

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615859

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615860

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615861

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'bpm'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615862

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615863

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'breaths/min'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615864

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615866

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615867

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615868

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:24:07
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615869

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:24:07
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615870

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Post-Dose (POSTDOSE)'		28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615871

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615872

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615873

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615874

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '6 Aug 2020 18:30'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615875

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615876

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615877

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615878

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615879

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'bpm'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615880

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615881

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'breaths/min'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615882

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615883

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615884

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615885

US3272070
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	28 Aug 2020 19:58:10

FDA-CBER-2022-1614-1615886

US3272070
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:24:07
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615887

US3272070
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:24:07
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615888

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615890

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615891

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615892

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615894

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '06 Aug 2020 17:57'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615895

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615896

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		29 Oct 2020 19:08:08
User entered 'ONCE'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615897

US3272070
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615898

US3272070
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615899

US3272070
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615900

US3272070
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615901

US3272070
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '6 Aug 2020 17:04'	System	28 Aug 2020 19:58:47

FDA-CBER-2022-1614-1615902

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:24:07
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1615903

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615904

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered 'Yes (Y)'		28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615905

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered '16:51'		28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615906

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '6 Aug 2020 16:51'	System	28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615907

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615908

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered 'No (N)'		28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615909

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:18
User entered empty.		28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615910

US3272070
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	28 Aug 2020 19:59:09

FDA-CBER-2022-1614-1615911

US3272070
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:23
User entered 'Yes (Y)'		28 Aug 2020 19:59:14

FDA-CBER-2022-1614-1615912

US3272070
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 19:59:14

FDA-CBER-2022-1614-1615913

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615914

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615915

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615916

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615917

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615918

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 18:17'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615919

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 20:47'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615920

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615922

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615923

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615924

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615925

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615926

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615927

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 21:42'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615928

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615929

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 2'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615930

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615931

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615932

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615933

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615934

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615935

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615936

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 3'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615937

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615938

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615939

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615940

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615941

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615942

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615943

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 4'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615944

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615945

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615946

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615947

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615948

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615949

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615950

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 5'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615951

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615952

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615953

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615954

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615955

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615956

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615957

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 6'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615958

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615959

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615960

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615961

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615963

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615964

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615966

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615967

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615968

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615969

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615970

US3272070
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615971

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615972

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615974

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615975

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615977

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 18:17'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615978

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 20:47'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615979

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615980

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615981

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615982

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615983

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615984

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615985

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615986

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1615987

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 21:42'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615988

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615989

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 2'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615990

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615992

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615993

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615995

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615996

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615997

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 3'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1615998

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1615999

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616000

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616001

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616004

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616005

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 4'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616006

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616008

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616009

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616011

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616012

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616013

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 5'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616014

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616016

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616017

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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'	System	10 Aug 2020 17:04:49
User entered '10 Aug 2020 12:04'	System	10 Aug 2020 17:04:49

FDA-CBER-2022-1614-1616019

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616020

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616021

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616024

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616025

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616028

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616029

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 7'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616030

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616031

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616032

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616033

US3272070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616035

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616036

US3272070
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616037

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616038

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616040

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616041

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616042

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616043

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616044

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616045

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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'	System	06 Aug 2020 23:41:29
User entered '06 Aug 2020 18:41'	System	06 Aug 2020 23:41:29

FDA-CBER-2022-1614-1616046

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 18:17'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616047

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 20:47'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616048

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616049

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616050

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616051

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616052

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616053

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616054

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616055

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616056

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616057

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Aug 2020 21:42'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616058

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616059

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 2'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616060

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616062

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616063

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616064

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616065

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616066

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616067

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616068

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616069

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616070

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 3'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616071

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616072

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616074

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616075

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616076

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616077

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616078

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616080

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616081

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 4'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616082

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616083

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616084

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616085

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616086

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616087

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616088

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616089

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616090

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616091

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616092

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 5'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616093

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616094

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616095

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616096

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616097

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616098

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616099

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616100

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616101

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616102

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616103

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616105

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616106

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616107

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616108

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616109

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616110

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616111

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616112

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616113

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616114

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	06 Aug 2020 23:13:28
User entered 'Day 7'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616115

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616116

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616117

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616118

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616119

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616120

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616121

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616122

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616123

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616124

US3272070
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 23:13:28

FDA-CBER-2022-1614-1616125

US3272070
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:08:58
User entered 'Yes (Y)'		28 Aug 2020 20:00:04

FDA-CBER-2022-1614-1616126

US3272070
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616130

US3272070
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:00:09

FDA-CBER-2022-1614-1616131

US3272070
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616132

US3272070
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616134

US3272070
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616136

US3272070
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:00:28

FDA-CBER-2022-1614-1616137

US3272070
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616138

US3272070
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616141

US3272070
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616142

US3272070
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:00:47

FDA-CBER-2022-1614-1616143

US3272070
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616144

US3272070
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).		29 Oct 2020 15:48:48
User entered '3 Sep 2020' reason for change: Data Entry Error		04 Sep 2020 21:41:44
User entered '4 Sep 2020'		04 Sep 2020 21:38:59

FDA-CBER-2022-1614-1616145

US3272070
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616146

US3272070
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:24:07
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'VISIT2'	System	04 Sep 2020 21:38:59

FDA-CBER-2022-1614-1616147

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616148

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616149

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616150

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616151

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1616152

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616154

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616155

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616156

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'bpm'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616157

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616158

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'breaths/min'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616159

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616160

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616161

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616162

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616163

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Post-Dose (POSTDOSE)'		04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616164

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616165

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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'		04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616166

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616167

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1616168

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:09:52
User entered '36.8' C		04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616169

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616170

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616171

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616172

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'bpm'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616173

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616174

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'breaths/min'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616175

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616176

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616177

US3272070
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:24:07
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'mmHg'	System	04 Sep 2020 21:40:09

FDA-CBER-2022-1614-1616179

US3272070
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:24:07
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616180

US3272070
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:24:07
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).		29 Oct 2020 15:49:09
User entered '3 Sep 2020'		04 Sep 2020 21:42:00

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered 'Yes (Y)'		03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616182

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered empty.		03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616183

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616184

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616185

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).		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).	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

FDA-CBER-2022-1614-1616186

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616187

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '3 Sep 2020 14:52'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616188

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:00
User entered 'Left Arm (LEFT ARM)'		03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616189

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		29 Oct 2020 19:10:00
User entered 'ONCE'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616190

US3272070
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:24:07
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616191

US3272070
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616192

US3272070
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616193

US3272070
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616194

US3272070
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:24:07
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '3 Sep 2020 14:19'	System	04 Sep 2020 21:42:17

FDA-CBER-2022-1614-1616195

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:24:07
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616196

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616197

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered 'Yes (Y)'		04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616198

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered '14:05'		04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616199

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:24:07
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '3 Sep 2020 14:05'	System	04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616200

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616201

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered 'No (N)'		04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616202

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:24
User entered empty.		04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616203

US3272070
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 16:24:07
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	04 Sep 2020 21:42:30

FDA-CBER-2022-1614-1616204

US3272070
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per CDM: Please complete Visit 3 forms.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:45:31
Query 'Per CDM: Please complete Visit 3 forms.' answered with 'subject is deceased' (Site from DM).		29 Oct 2020 20:02:11
DataPoint Un-verified.		29 Oct 2020 20:01:52
User entered 'No (N)' reason for change: Data Entry Error		29 Oct 2020 20:01:52
DataPoint Verified.		29 Oct 2020 19:10:28
User opened query 'Per CDM: Please complete Visit 3 forms.' (Site from DM).		29 Oct 2020 15:49:51
User entered 'Yes (Y)'		04 Sep 2020 21:42:34

US3272070
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	29 Oct 2020 20:01:52
User entered '1'	System	04 Sep 2020 21:42:34

FDA-CBER-2022-1614-1616206

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616207

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616208

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616209

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616210

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616211

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 15:12'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616212

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616213

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616214

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616215

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616216

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616217

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616218

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616219

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616220

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616221

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616222

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 2'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616223

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616224

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616225

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616226

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616227

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616228

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616229

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616230

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616231

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 3'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616232

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616233

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616234

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616235

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616236

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616237

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616238

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 4'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616239

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616240

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616241

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616242

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616243

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616244

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616245

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 5'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616246

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616247

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616248

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616249

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616250

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616251

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616252

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 6'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616253

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616254

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616255

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616256

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616257

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616258

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616259

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 7'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616260

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616261

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616262

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616263

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616264

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616265

US3272070
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616266

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616267

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616269

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616270

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616272

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 15:12'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616273

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616274

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616275

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616276

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616277

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616278

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616279

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616280

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616281

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616282

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616283

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616284

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 2'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616285

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616286

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616287

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616288

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616289

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616290

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616291

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616292

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616293

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616294

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 3'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616295

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616297

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616298

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616300

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616301

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616302

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 4'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616303

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616304

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616305

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616306

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616307

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616308

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616309

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616310

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 5'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616311

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616312

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616313

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616314

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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'	System	07 Sep 2020 17:06:15
User entered '07 Sep 2020 12:06'	System	07 Sep 2020 17:06:15

FDA-CBER-2022-1614-1616316

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616317

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616318

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 6'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616319

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616320

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616321

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616322

US3272070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616324

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616325

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616326

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 7'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616327

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616328

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616329

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616330

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616331

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616332

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616333

US3272070
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616334

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616335

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616336

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616337

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616338

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616339

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616340

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616341

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616342

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616343

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 15:12'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616344

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616345

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616346

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616347

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616348

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616349

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616350

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616351

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616352

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616353

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616354

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616355

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616356

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 2'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616357

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616358

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616359

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616360

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616361

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616362

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616363

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616364

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616365

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616366

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616367

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 3'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616368

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616369

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616370

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616371

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616372

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616373

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616374

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616375

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32

FDA-CBER-2022-1614-1616376

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616377

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616378

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 4'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616379

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616380

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616381

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616382

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616383

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616384

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616385

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616386

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616387

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616388

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616389

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 5'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616390

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616391

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616392

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616393

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616394

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616395

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616396

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616397

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616398

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616399

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616400

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 6'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616401

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616402

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616403

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616404

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616405

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616406

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616407

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616408

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616409

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616410

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616411

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
Data entry locked.	System	03 Sep 2020 19:57:19
User entered 'Day 7'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616412

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616413

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616414

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616415

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616416

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616417

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616418

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616419

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
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

FDA-CBER-2022-1614-1616420

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616421

US3272070
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:24:07
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:36:32
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:57:19

FDA-CBER-2022-1614-1616422

US3272070
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:10:57
User entered 'Yes (Y)'		10 Sep 2020 15:02:46

FDA-CBER-2022-1614-1616423

US3272070
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616425

US3272070
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:00
User entered 'Yes (Y)'		10 Sep 2020 15:02:51

FDA-CBER-2022-1614-1616427

US3272070
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	10 Sep 2020 15:02:51

FDA-CBER-2022-1614-1616428

US3272070
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered 'Yes (Y)'		17 Sep 2020 17:21:44

FDA-CBER-2022-1614-1616429

US3272070
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered '17 Sep 2020'		17 Sep 2020 17:21:44

US3272070
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered 'Contact Made (CONTACT MADE)'		17 Sep 2020 17:21:44

FDA-CBER-2022-1614-1616431

US3272070
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:09
User entered empty.		17 Sep 2020 17:21:44

FDA-CBER-2022-1614-1616432

US3272070
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616433

US3272070
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	17 Sep 2020 17:21:47

FDA-CBER-2022-1614-1616434

US3272070
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered 'Yes (Y)'		24 Sep 2020 18:43:55

US3272070
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered '24 Sep 2020'		24 Sep 2020 18:43:55

US3272070
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered 'Contact Made (CONTACT MADE)'		24 Sep 2020 18:43:55

US3272070
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:24:07
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:18
User entered empty.		24 Sep 2020 18:43:55

US3272070
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:22
User entered 'Yes (Y)'		24 Sep 2020 18:43:59

FDA-CBER-2022-1614-1616439

US3272070
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:24:07
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	24 Sep 2020 18:43:59

FDA-CBER-2022-1614-1616440

US3272070
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:24:07
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616441

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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

FDA-CBER-2022-1614-1616442

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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: 09 Jun 2021 16:24:07
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616444

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616445

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616447

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616448

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	02 Oct 2020 15:11:06
User entered '1 Oct 2020 10:00'	System	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616449

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616450

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616451

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616452

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616453

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616454

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616455

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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).		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 '1'	Kayla Flege (b) (4) (b) (4)	02 Oct 2020 15:10:42

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616457

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616458

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616459

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616460

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616461

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616462

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616463

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616464

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616466

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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) (b) (4)	02 Oct 2020 15:10:42

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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).		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) (b) (4)	02 Oct 2020 15:10:42

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	02 Dec 2020 19:59:10
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:59:10
Signature has been broken.	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:59:10
User entered '0' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:59:10
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	02 Dec 2020 19:58:58
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'	Kayla Flege (b) (4) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616469

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:58:58
Signature has been broken.	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:58:58
User entered '1' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:58:58
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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616470

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:58:58
Signature has been broken.	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:58:58
User entered '1' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:58:58
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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616471

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616472

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
DataPoint Verified.		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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616473

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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).		24 Nov 2020 02:50:35
User closed query 'PV Query: It was reported that th chest x-ray was performed. Please provide the chest x-ray results when available.' (Site from Safety).		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).		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).		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).		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).		20 Nov 2020 21:05:25

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
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).	(b) (4), (b) (6)	20 Nov 2020 21:05:18
DataPoint Verified.		20 Nov 2020 18:59:11
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).		13 Nov 2020 15:36:59
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).		13 Nov 2020 15:36:51
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).		13 Nov 2020 15:36:38
User closed query 'PV Query: Please provide the clinical course of the event, including signs or symptoms.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:43:09
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).		06 Nov 2020 14:43:05
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 14:43:00

FDA-CBER-2022-1614-1616475

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
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).		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).		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).		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).		23 Oct 2020 16:59:25

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
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).		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).		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).		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).		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

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
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

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
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 infarcion' (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).		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).		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).		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

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
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).		12 Oct 2020 14:48:47
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).		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) (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) (b) (4)	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616480

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616481

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	02 Oct 2020 15:10:42

FDA-CBER-2022-1614-1616482

US3272070
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:24:07
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26

FDA-CBER-2022-1614-1616483

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).		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)'		28 Aug 2020 20:01:19

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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)	11 Dec 2020 15:08:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 15:08:49
Data point term sent to Coder	System	11 Dec 2020 15:08:03
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:07:58
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	System	20 Nov 2020 19:33:05
Coding entries removed.	(b) (4), (b) (6)	20 Nov 2020 19:32:27
DataPoint Verified.		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	System	27 Oct 2020 15:52:51
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	27 Oct 2020 15:52:08

FDA-CBER-2022-1614-1616485

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:07

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)	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	System	21 Sep 2020 22:35:23
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 22:34:53
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)	28 Aug 2020 20:03:44

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616487

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per DM CLR: Please update the indication and clarify the location of NEUROPATHY (Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:33:29
User closed query 'Per DM CLR: Please update the indication and clarify the location of NEUROPATHY (Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:32:28
Query 'Per DM CLR: Please update the indication and clarify the location of NEUROPATHY (Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:08:07
Query 'Per DM CLR: Please update the indication and clarify the location of NEUROPATHY (Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:08:03
User entered 'Type 2 Diabetes Mellitus' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:07:58
User opened query 'Per DM CLR: Please update the indication and clarify the location of NEUROPATHY (Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 10:27:45
User opened query 'Per DM CLR: Please update the indication and clarify the location of NEUROPATHY (Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 10:26:23

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:07

Indication

Audit	User	Time (GMT)
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:26:58
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).		25 Nov 2020 16:26:56
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).	(b) (4), (b) (6)	20 Nov 2020 19:32:52
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 19:32:27
User entered 'Diabetic Neuropathy.' reason for change: Data Entry Error		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).		12 Nov 2020 05:25:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
Query 'Per MM: Please clarify indication.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	27 Oct 2020 15:52:14
User entered 'Type 2 diabetes mellitus' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Oct 2020 15:52:08
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).		23 Oct 2020 13:40:14

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:07

Indication

Audit	User	Time (GMT)
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
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).		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: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '75'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616491

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616492

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616493

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616494

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616495

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616496

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616497

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616498

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616499

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616500

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616501

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616502

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616503

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616504

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:03:44

FDA-CBER-2022-1614-1616505

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616506

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616507

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'hypercholesterolemia'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616508

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616509

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616510

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616511

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616512

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616513

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616514

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616515

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'		28 Aug 2020 20:04:53

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616517

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616518

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616519

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616520

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616521

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616522

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:04:53

FDA-CBER-2022-1614-1616523

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616524

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616525

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).	(b) (4), (b) (6)	13 Nov 2020 18:37:24
DataPoint Verified.	(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 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).		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

FDA-CBER-2022-1614-1616526

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '300'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616527

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616528

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616529

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'twice daily (BID)'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616530

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616531

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616532

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616533

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2008'		28 Aug 2020 20:05:53

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616535

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616536

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616537

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616538

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2'	System	28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616539

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616540

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:05:53

FDA-CBER-2022-1614-1616541

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616542

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616543

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'diabetes mellitus type 2'		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616544

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)' reason for change: Data Entry Error		21 Sep 2020 22:36:31
User entered 'IU (IU)'		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616546

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'units' reason for change: Data Entry Error		21 Sep 2020 22:36:31
User entered empty.		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616547

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616548

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616549

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Subcutaneous (SUBCUTANEOUS)'		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616550

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616551

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2000'		28 Aug 2020 20:06:59

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616553

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616554

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:06:59

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616557

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616558

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:06:59

FDA-CBER-2022-1614-1616559

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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	System	21 Sep 2020 22:44:34
Coding entries removed.	(b) (4), (b) (6)	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	System	28 Aug 2020 20:08:26
User entered 'losartan'	(b) (4), (b) (6)	28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616560

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616561

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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)	13 Nov 2020 18:37:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'hypertension' reason for change: Data Entry Error		21 Sep 2020 22:44:14
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 'per patient used for this indication' (Site from DM).		21 Sep 2020 22:37:05
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 05:19:57
User entered 'diabetes mellitus type 2'	(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: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).	(b) (4), (b) (6)	11 Nov 2020 11:14:14
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 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).		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: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:08:21

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616565

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'twice daily (BID)'		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616566

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616567

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616568

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616569

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2018'		28 Aug 2020 20:08:21

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616571

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616572

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616573

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:08:21

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2'	System	28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616575

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616576

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:08:21

FDA-CBER-2022-1614-1616577

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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) (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) (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

FDA-CBER-2022-1614-1616578

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616579

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616582

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616583

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'twice daily (BID)'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616584

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616585

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616586

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:09:34

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 1987'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616588

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616589

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616590

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616591

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616592

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '2'	System	28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616593

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616594

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:09:34

FDA-CBER-2022-1614-1616595

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616596

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616599

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616601

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616602

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616604

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616606

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616608

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616610

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:12:05

FDA-CBER-2022-1614-1616611

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:12:05

FDA-CBER-2022-1614-1616612

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:12:05

FDA-CBER-2022-1614-1616613

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616614

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616615

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616616

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616617

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).		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).		17 Sep 2020 05:17:42
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616618

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mcg' reason for change: Data Entry Error		21 Sep 2020 22:40:44
User entered empty.		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616619

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616620

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616621

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616622

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616623

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2010'		28 Aug 2020 20:14:36

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616625

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616626

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616627

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616628

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616629

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616630

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:14:36

FDA-CBER-2022-1614-1616631

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616632

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616633

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'diabetes mellitus type 2'		28 Aug 2020 20:15:31

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '25'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616635

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616636

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616637

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:15:31

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616639

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616640

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616641

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2019'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616642

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616643

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616644

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616645

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:15:31

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616647

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616648

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:15:31

FDA-CBER-2022-1614-1616649

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616650

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616651

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'hypertension'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616652

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '25'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616653

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616654

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616655

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616656

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616657

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616658

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616659

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 2017'		28 Aug 2020 20:16:36

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616661

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616662

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:16:36

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:16:36

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616665

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616666

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:16:36

FDA-CBER-2022-1614-1616667

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616668

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616669

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'cardiac prophylaxis'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616670

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '21'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616671

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616672

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616673

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once daily (QD)'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616674

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616675

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Oral (ORAL)'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616676

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616677

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'UN UNK 1987'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616678

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616679

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Yes (Y)'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616680

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616681

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616682

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616683

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '1'	System	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616684

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '804 (804)'	System	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-1616685

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616686

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616687

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616688

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 81mg; 325mg; 500mg)or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 12:18:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 81mg; 325mg; 500mg)or provide explanation for alternate dosage. ' answered with 'this dosage is correct per pt ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 21:29:21
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 81mg; 325mg; 500mg)or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 12:45:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '300'		21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616689

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616690

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616691

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616692

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616694

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616695

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616696

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616698

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616699

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:49:56
Query 'Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:41
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:36
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:36
User opened query 'Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:31:21
User closed 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)	27 Nov 2020 16:31:21
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 21:17:24
DataPoint Verified.	(b) (4), (b) (6)	9 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).		8 Oct 2020 16:28:46
User entered 'Yes (Y)'	(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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616701

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616702

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:24:18

FDA-CBER-2022-1614-1616703

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616704

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616705

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616706

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616707

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616708

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616709

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'other (OTHER)'		21 Oct 2020 02:28:15

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'TITRATION DRIP'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616711

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616712

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:28:15

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:28:15

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616715

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616716

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616717

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:50:34
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:52
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:48
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:48
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:31:34
User closed 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)	27 Nov 2020 16:31:34
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 21:16:23
DataPoint Verified.		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).		28 Oct 2020 16:28:58
User entered 'Yes (Y)'	(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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616719

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616720

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:28:15

FDA-CBER-2022-1614-1616721

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616722

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616723

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:29:40

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '2.5'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616725

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mg (mg)'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616726

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616727

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616728

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616729

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616730

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'INTRA ARTERIAL'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616731

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616732

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616733

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616734

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616735

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:51:28
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:02
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:58
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:24:58
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:32:09
User closed 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).		27 Nov 2020 16:32:09
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 21:18:02
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).		28 Oct 2020 16:29:10
User entered 'Yes (Y)'	(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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616737

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616738

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:29:40

FDA-CBER-2022-1614-1616739

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616740

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616741

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616742

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616743

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616744

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616746

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616748

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616750

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616753

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:51:52
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:12
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:08
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:08
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:32:15
User closed 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)	27 Nov 2020 16:32:15
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).		28 Oct 2020 16:29:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:31:08

FDA-CBER-2022-1614-1616754

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:31:08

FDA-CBER-2022-1614-1616755

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:31:08

FDA-CBER-2022-1614-1616756

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:31:08

FDA-CBER-2022-1614-1616757

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616758

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616759

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:32:04

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '999'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616761

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mL (mL)'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616762

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616763

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616764

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616765

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616766

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616767

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:32:04

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616769

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616770

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616771

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:52:09
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:21
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:18
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:18
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:32:20
User closed 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)	27 Nov 2020 16:32:20
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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616773

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616774

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:32:04

FDA-CBER-2022-1614-1616775

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616776

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616778

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:37
User entered '100' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '1000'		21 Oct 2020 02:33:13

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:07

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:46:02
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:41
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:37
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:37
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 12:45:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'mL (mL)'		21 Oct 2020 02:33:13

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:37
User entered 'units' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:11:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:33:13

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'		21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616782

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616783

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'		21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616784

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'INTRA ARTERIAL'		21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616785

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616786

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616789

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:53:26
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:30
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:26
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:26
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:32:42
User closed 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)	27 Nov 2020 16:32:42
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).		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

US3272070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:07

Was this medication taken for solicited event?

Audit	User	Time (GMT)
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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616792

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616793

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:33:13

FDA-CBER-2022-1614-1616794

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616795

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616796

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:34:08

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '100'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616798

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616799

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MCG'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616800

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'once (ONCE)'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616801

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616802

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Intravenous (INTRAVENOUS)'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616803

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered empty.		21 Oct 2020 02:34:08

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616805

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '0'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616806

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616807

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '01 Oct 2020'		21 Oct 2020 02:34:08

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:53:47
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:42
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:38
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:38
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:32:55
User closed 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)	27 Nov 2020 16:32:55
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 21:19:29
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).		28 Oct 2020 16:30:14
User entered 'Yes (Y)'	(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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616810

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616811

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:34:08

FDA-CBER-2022-1614-1616812

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
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)	30 Mar 2021 13:55:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:55:11
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616813

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616814

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616817

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616819

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616823

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616826

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:54:16
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:56
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:47
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:25:47
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:33:07
User closed 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)	27 Nov 2020 16:33:07
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 21:19:52
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).		28 Oct 2020 16:30:25
User entered 'Yes (Y)'	(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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:35:09

FDA-CBER-2022-1614-1616828

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:35:09

FDA-CBER-2022-1614-1616829

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:35:09

FDA-CBER-2022-1614-1616830

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616831

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616832

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616837

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616838

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616839

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616840

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616841

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616842

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616843

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616844

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:54:35
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:13
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:10
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:10
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:33:12
User closed 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)	27 Nov 2020 16:33:12
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).		28 Oct 2020 16:30:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:36:40

FDA-CBER-2022-1614-1616845

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:36:40

FDA-CBER-2022-1614-1616846

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:36:40

FDA-CBER-2022-1614-1616847

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:36:40

FDA-CBER-2022-1614-1616848

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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 'NOREPINEPHRINE'	(b) (4), (b) (6)	21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616849

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'No (N)'		21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616850

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MYOCARDIAL INFARCTION'		21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616851

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered '30'		21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616852

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'Other (OTHER)'		21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616853

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:15:41
User entered 'MCG'		21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616854

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616856

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616857

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616858

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616859

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616861

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:54:53
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:21
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:18
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:18
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:33:18
User closed 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)	27 Nov 2020 16:33:18
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).		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: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616864

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616865

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:39:16

FDA-CBER-2022-1614-1616866

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616867

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616868

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616869

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616871

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616872

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616873

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616875

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616876

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616877

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616878

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616879

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616880

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:55:14
Query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:32
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:28
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 20:26:28
User opened query ' Per CDM RQ: Previous response is noted however Solicited event should be NO for recorded indication' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:33:23
User closed 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)	27 Nov 2020 16:33:23
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.		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).		28 Oct 2020 16:31:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 02:42:26

FDA-CBER-2022-1614-1616881

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:42:26

FDA-CBER-2022-1614-1616882

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:42:26

FDA-CBER-2022-1614-1616883

US3272070
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 16:24:07
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered empty.	System	21 Oct 2020 02:42:26

FDA-CBER-2022-1614-1616884

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 16:24:07
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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).		20 Nov 2020 18:59:55
User closed query 'Subject had concomitant procedures completed including, 1. Intubation with Mechanical ventilation 10/1 2. Cardiac catherization Consider adding to the CRF. ' (Site from CRA).		20 Nov 2020 18:59:48
User entered 'Yes (Y)' reason for change: Data Entry Error		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 catherization 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 catherization Consider adding to the CRF. ' (Site from CRA).		14 Oct 2020 16:45:12
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:27:04

FDA-CBER-2022-1614-1616885

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'		21 Oct 2020 02:44:59

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'INTUBATION'		21 Oct 2020 02:44:59

FDA-CBER-2022-1614-1616887

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'		21 Oct 2020 02:44:59

FDA-CBER-2022-1614-1616888

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 16:24:07
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.		21 Oct 2020 02:44:59

FDA-CBER-2022-1614-1616889

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'		21 Oct 2020 02:45:17

FDA-CBER-2022-1614-1616890

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'MECHANICAL VENTILATON'		21 Oct 2020 02:45:17

FDA-CBER-2022-1614-1616891

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:02:49
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'udpated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	02 Dec 2020 19:59:24
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:34:45
DataPoint Verified.		20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'		21 Oct 2020 02:45:17

FDA-CBER-2022-1614-1616892

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 16:24:07
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.		21 Oct 2020 02:45:17

FDA-CBER-2022-1614-1616893

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'		21 Oct 2020 02:45:41

FDA-CBER-2022-1614-1616894

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'ARTERIAL LINE INSERTION'		21 Oct 2020 02:45:41

FDA-CBER-2022-1614-1616895

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'		21 Oct 2020 02:45:41

FDA-CBER-2022-1614-1616896

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 16:24:07
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.		21 Oct 2020 02:45:41

FDA-CBER-2022-1614-1616897

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'		21 Oct 2020 02:46:02

FDA-CBER-2022-1614-1616898

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'CENTRAL VENOUS CATHETER INSERTION'		21 Oct 2020 02:46:02

FDA-CBER-2022-1614-1616899

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'		21 Oct 2020 02:46:02

FDA-CBER-2022-1614-1616900

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 16:24:07
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.		21 Oct 2020 02:46:02

FDA-CBER-2022-1614-1616901

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered '01 Oct 2020'		21 Oct 2020 02:46:26

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 16:24:07
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'CORONARY CATHETERIZATION'		21 Oct 2020 02:46:26

FDA-CBER-2022-1614-1616903

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 16:24:07
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered 'Adverse Event (AE)'		21 Oct 2020 02:46:26

FDA-CBER-2022-1614-1616904

US3272070
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 16:24:07
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:00:15
User entered empty.		21 Oct 2020 02:46:26

FDA-CBER-2022-1614-1616905

US3272070
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:24:07
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:38
User entered '01 Oct 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:38
DataPoint Verified.	(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) (b) (4)	12 Oct 2020 16:48:22
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) (b) (4)	12 Oct 2020 16:47:56

FDA-CBER-2022-1614-1616906

US3272070
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:24:07
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616907

US3272070

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:24:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

US3272070
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:24:07
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
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
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

FDA-CBER-2022-1614-1616910

US3272070
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:24:07
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:56
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered 'Myocardial Infarction'	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: 09 Jun 2021 16:24:07
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:01:40
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:30
User entered '01 Oct 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	21 Nov 2020 14:15:30
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:19:07
User entered '1 Oct 2020'	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: 09 Jun 2021 16:24:07
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616913

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		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: 09 Jun 2021 16:24:07
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	9 Oct 2020 19:17:43
Reviewed for Safety.		2 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616915

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		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: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616919

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616920

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616921

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	9 Oct 2020 19:17:43
Reviewed for Safety.		2 Oct 2020 16:54:43
User entered 'Adam'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616922

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616923

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered '2444 W. Faidley Ave'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616924

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'Grand Island'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616925

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'NE'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616926

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered '68803'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616927

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		16 Oct 2020 13:13:51
User entered 'US'	System	02 Oct 2020 16:54:50

FDA-CBER-2022-1614-1616928

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '5'	System	03 Dec 2020 15:40:42
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

FDA-CBER-2022-1614-1616929

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616930

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616931

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		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: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616933

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616936

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616937

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616938

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'Brosz'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616939

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616940

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616941

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616942

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616943

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616944

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '5'	System	03 Dec 2020 15:40:42
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

FDA-CBER-2022-1614-1616945

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:24:07
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616946

US3272070

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

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		16 Oct 2020 13:13:51
User entered '1'		02 Oct 2020 16:54:50

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'		02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616948

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616950

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616955

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616956

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616958

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616960

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616962

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '5'	System	03 Dec 2020 15:40:42
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

FDA-CBER-2022-1614-1616963

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:24:07
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 14:43:22
DataPoint Verified.		29 Oct 2020 19:17:43
User entered '1'		16 Oct 2020 13:13:59

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'USA-US070-2020-MRNA-1273-P301000003'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616966

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616967

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'Yes (Y)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616968

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		02 Oct 2020 16:54:43
User entered 'No (N)'	System	02 Oct 2020 16:54:22

FDA-CBER-2022-1614-1616969

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:17:43
Reviewed for Safety.		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: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616973

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616976

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616978

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616980

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '5'	System	03 Dec 2020 15:40:42
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: 09 Jun 2021 16:24:07
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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 '1'	(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: 09 Jun 2021 16:24:07
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616986

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616992

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616993

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1616998

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '5'	System	03 Dec 2020 15:40:42
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

FDA-CBER-2022-1614-1616999

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:24:07
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:40:34
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 02:50:54

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1617004

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1617010

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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: 09 Jun 2021 16:24:07
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
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

FDA-CBER-2022-1614-1617016

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 16:24:07
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User entered '5'	System	03 Dec 2020 15:40:42
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

FDA-CBER-2022-1614-1617017

US3272070
Folder: SAE USA-US070-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 16:24:07
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User entered '03/Dec/2020 15:40'	System	03 Dec 2020 15:40:42

FDA-CBER-2022-1614-1617018

US3272070

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

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:24:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:27:26
User signature succeeded.	Adam Brosz (b) (4)	14 Mar 2021 17:23:21
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 15:40:42