US3032277 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:54:17

All time stamps listed in this document are displayed in GMT

Participant ID   US3032277

mRNA-1273-P301 Completion Guidelines

US3032277

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3032277

Folder: Screening

Form: Demographics

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Date of Birth (MMM yyyy)	(b) (6) 1929
Age	90
Age Units	YEARS
Age (Derived)	90
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

US3032277

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Date of Informed Consent *(dd MMM yyyy)*	20 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

Did the participant meet all eligibility criteria?   Yes ●

No ◯

Were any significant conditions reported?   Yes ●

No ○

US3032277

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Condition	HYPERTENSION
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)	

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3032277

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

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)	

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4)   **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Condition	KIDNEY FAILURE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3032277

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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US3032277

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Condition	CAPOTEN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

US3032277

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3032277

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

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

Condition	BLOOD CLOT-RIGHT LOWER LEG
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3032277

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3032277

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **08 Oct 2020 15:47:19**

Generated On: 09 Jun 2021 14:54:17

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	15:30 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:30
Height *(xxx.x)*	168.9 cm
Weight *(xxx.x)*	59.9 kg
BMI *(xxx.x)*	20.99750 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)	

US3032277

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   20 AUG 2020

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

US3032277

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ◯ No ⬤
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ◯ No ⬤
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ◯ No ⬤
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ◯ No ⬤
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ◯ No ⬤
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ◯ No ⬤
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ◯ No ⬤
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ◯ No ⬤
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ◯ No ⬤
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ◯ No ⬤
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ◯ No ⬤
Other	Yes ⬤ No ◯
Specify	GROCERY SHOPPING AND OUT WITH FRIENDS, WEARS MASK 50% OF THE TIME

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

US3032277

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3032277

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **28 Sep 2020 17:59:35**

Generated On: 09 Jun 2021 14:54:17

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **02 Nov 2020 22:20:13**

Generated On: 09 Jun 2021 14:54:17

What was the date of randomization? *(dd MMM yyyy)*	20 AUG 2020
What was the participant's randomization number?	187442

In what Cohort was the participant enrolled?

- ○ >=18 and <65 years and not at risk
- ○ >=18 and <65 years and at risk
- ● >=65 years

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ○ No ●	
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ○ No ●	
Severe obesity (body mass index > or = 40kg/m2)	Yes ○ No ●	
Diabetes (Type I, Type 2, or gestational)	Yes ● No ○	
Liver Disease	Yes ○ No ●	
Human Immunodeficiency Virus (HIV) infection	Yes ○ No ●	

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Height	ND - Not Done
Weight	ND - Not Done

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

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)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	15:30 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:30
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)   **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

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)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	17:58 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 17:58
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⚫
	Axillary ⚪
	Other ⚪
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

US3032277

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Was the physical examination performed?   Yes ●

                                                           No ○

Date of examination *(dd MMM yyyy)*   20 AUG 2020

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

US3032277
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) 28 Sep 2020 17:59:24
Generated On: 09 Jun 2021 14:54:17

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)*	20 AUG 2020
What was the treatment time? *(00:00-23:59)*	17:08 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 17:08

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

US3032277

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	20 AUG 2020
Collection time *(00:00-23:59)*	16:23 (24 HR)
Collection date and time (derived)	20 AUG 2020 16:23

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Collection date *(dd MMM yyyy)*   20 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:07	20 AUG 2020 16:07
Nasopharyngeal Swab 2	No		

US3032277

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 17:56
PC Open Date & Time	20 AUG 2020 17:28
PC Close Date & Time	20 AUG 2020 19:58

FDA-CBER-2022-1614-0165919

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	20 AUG 2020 20:53
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-0165920

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	21 AUG 2020 16:54
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

TIMEPOINT	**DAY 3**

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.5 °F

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

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

PC Time Stamp	22 AUG 2020 16:44
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0165922

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT	DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °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	23 AUG 2020 17:07
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 AUG 2020 17:03
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:17

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	25 AUG 2020 19:15
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

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**	98.1 °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	26 AUG 2020 17:53
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:17

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	20 AUG 2020 17:58
PC Open Date & Time	20 AUG 2020 17:28
PC Close Date & Time	20 AUG 2020 19:58

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:17

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	20 AUG 2020 20:53
PC Close Date & Time	21 AUG 2020 11:59

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

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	21 AUG 2020 16:55
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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	22 AUG 2020 16:46
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

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	23 AUG 2020 17:08
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

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	24 AUG 2020 17:03
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.**	None ⬤
Please select one response below	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**	None ⬤
Please select one response below	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	25 AUG 2020 19:16
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

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	26 AUG 2020 17:54
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17

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 ◯

Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ● |
| | Yes ○ |

PC Time stamp	20 AUG 2020 18:00
PC Open Date & Time	20 AUG 2020 17:28
PC Close Date & Time	20 AUG 2020 19:58

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 ○

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯ Yes ◯
PC Time stamp	
PC Open Date & Time	20 AUG 2020 20:53
PC Close Date & Time	21 AUG 2020 11:59

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:17

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 ●

	Yes ◯
PC Time stamp	21 AUG 2020 16:56
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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	22 AUG 2020 16:47
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17

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 ●

	Yes ◯
PC Time stamp	23 AUG 2020 17:09
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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 ●

Yes ◯

PC Time stamp	24 AUG 2020 17:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:17

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 ●

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:17

	Yes ◯
PC Time stamp	25 AUG 2020 19:17
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:17

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 ●

	Yes ◯
PC Time stamp	26 AUG 2020 17:55
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032277

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

| 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

US3032277

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3032277
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **28 Sep 2020 17:59:24**
Generated On: 09 Jun 2021 14:54:17

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 03 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3032277

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?   Yes ⬤

                                                                                    No ◯

Continuing Flag   1

US3032277

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

| 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 _____

US3032277

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?   Yes ◯

                                                                          No ⬤

Continuing Flag

US3032277

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

Form: Visit Date

Data signed: (b) (4) **18 Mar 2021 21:28:20**

Generated On: 09 Jun 2021 14:54:17

Was this visit performed?	Yes ◯
	No ⬤

Visit date (dd MMM yyyy) _____

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

Folder OID	UNBLND_DECIDE

US3032277

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

Did the participant experience any adverse events?　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

If Yes, enter details on the Adverse Events form.

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

AEID	USA-US032-2020-MRNA-1273-P30 1000003
Adverse event	ACUTE DUODENAL ULCER WITH HEMORRHAGE

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)*	12 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ◯ No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	17 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ◯ Grade 2/Moderate ◯ Grade 3/Severe ◯ Grade 4 ⬤

Is the adverse event serious? Yes ⬤ No ◯

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	12 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	17 SEP 2020

Admitted to ICU? Yes ◯ No ⬤ Unknown ◯

PRODUCTION RELEASE (v12.003 EAB) (1725)

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 CALLED SITE TO REPORT BEING ADMITTED TO HOSPITAL FOR THE SAE. SUBJECT IS STILL THERE AND PLANS ON BEING RELEASE IN THE MORNING ON 15 SEP 2020. SITE IS SENDING A FORM FOR MEDICAL RELEASE.- UPDATE- SUBJECT WENT TO ER AND GOT ADMITTED ON 12/SEP/2020. FOR A GASTROINTESTINAL BLEED. SUBJECT WAS DISMISSED TO HOME ON 17/SEP/2020.

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)	0

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **28 Sep 2020 17:59:24**

Generated On: 09 Jun 2021 14:54:17

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

No ○

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	ASPIRIN

Prophylaxis   Yes ●

                  No ◯

Indication	BLOOD CLOTS
Dose per administration	325

Dose unit   mg ●

                  ug ◯

                  mL ◯

                  g ◯

                  IU ◯

                  tablet ◯

                  capsule ◯

                  puff ◯

                  Other ◯

If dose unit is Other, specify

Frequency   once daily ●

                  twice daily ◯

                  three times daily ◯

                  four times daily ◯

                  every other day ◯

                  every week ◯

                  every month ◯

                  as needed ◯

                  once ◯

                  unknown ◯

                  other ◯

If frequency is Other, specify

Route of administration   Oral ●

                  Topical ◯

                  Subcutaneous ◯

                  Transdermal ◯

                  Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperitoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2013
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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	ALLOPURINOL

Prophylaxis

Yes ◯

No ⬤

Indication	GOUT BILATERAL FEET
Dose per administration	150

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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

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

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EAB) (1725)

	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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	PRAVASTATIN

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 ●

FDA-CBER-2022-1614-0165970

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	LOSARTAN

Prophylaxis	Yes ⬤ No ●

Indication	HYPERTENSION
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-2022-1614-0165971

	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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	GLIMEPIRIDE

Prophylaxis	Yes ⚪
	No ⚫

Indication	DIABETES MELLITUS TYPE 2
Dose per administration	3

Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify	

Frequency	once daily ⚫
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪

If frequency is Other, specify	

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

FDA-CBER-2022-1614-0165973

	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 2005
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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	FINASTRIDE

Prophylaxis	Yes ◯
	No ●

Indication	ENLARGED PROSTATE
Dose per administration	5

Dose unit	
	mg ●
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify _____

Frequency	
	once daily ●
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify _____

Route of administration	
	Oral ●
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

	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 2005
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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	CARVEDILOL

Prophylaxis	
Yes	⚪
No	⬤

Indication	HYPERTENSION

Dose per administration	6.25

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 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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	VITAMIN B12

Prophylaxis	Yes ●
	No ○

Indication	NUTRITIONAL SUPPLEMENT

Dose per administration	250

Dose unit	mg ○
	ug ●
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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 1998
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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	ATROVENT
Prophylaxis	Yes ⭕
	No ⬤
Indication	SEASONAL ALLERGIES
Dose per administration	2
Dose unit	mg ⭕
	ug ⭕
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⬤
If dose unit is Other, specify	PUFFS
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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4)   **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	PACKED RED BLOOD CELLS

Prophylaxis	
	Yes ◯
	No ⬤

Indication	ACUTE DUODENAL ULCER WITH HEMORRHAGE

Dose per administration	1

Dose unit	
	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤

If dose unit is Other, specify	UNIT

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)*	13 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 SEP 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 ◯

FDA-CBER-2022-1614-0165984

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	PANTOPRAZOLE

Prophylaxis

Yes ◯
No ⬤

Indication

ACUTE DUODENAL ULCER
WITH HEMORRHAGE

Dose per administration   40

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ⬤
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ◯
Transdermal ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **12 Feb 2021 19:57:06**
Generated On: 09 Jun 2021 14:54:17

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)*	13 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 SEP 2020
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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **12 Feb 2021 19:57:06**

Generated On: 09 Jun 2021 14:54:17

Name of Medication	PANTOPRAZOLE

Prophylaxis	
	Yes ○
	No ●

Indication	ACUTE DUODENAL ULCER WITH HEMORRHAGE

Dose per administration	40

Dose unit	
	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	
	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify	

Route of administration	
	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

Intraocular	◯
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)*	12 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 SEP 2020
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 ⬤

FDA-CBER-2022-1614-0165988

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Were any concomitant procedures performed?   Yes ●

                                                             No ◯

If yes, please complete Concomitant Procedures form.

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
14 SEP 2020	ESOPHAGASTRODUODENALSCOPY	Adverse Event	
14 SEP 2020	COLONOSCOPY	Adverse Event	
14 SEP 2020	TRANSFUSION OF PACKED RED BLOOD CELLS	Adverse Event	

US3032277

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) **18 Mar 2021 21:28:20**

Generated On: 09 Jun 2021 14:54:17

Date of dosing discontinuation (dd MMM yyyy)	1 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	◯
SAE (specify)	⬤
Death	◯
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	◯
Due to SARS-COV-2	◯
Other	◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	#1 FOR ROW 1

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) **08 Dec 2020 19:48:36**

Generated On: 09 Jun 2021 14:54:17

Date of study discontinuation/completion *(dd MMM yyyy)*	1 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	SAE #1

If reason for discontinuation is Death, main cause of death

Adverse event	◯
Unknown	◯
Other	◯

If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	

Was autopsy performed?

Yes	◯
No	◯
Unknown	◯

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	15/SEP/2020 11:45
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

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Data signed: (b) (4) **30 Jan 2021 16:53:32**
Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/OCT/2020 09:56
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

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4)   **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/OCT/2020 22:48
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

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/NOV/2020 15:16
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

FDA-CBER-2022-1614-0165998

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: [(b) (4)] **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	13/NOV/2020 17:51
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

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4)   **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	30/NOV/2020 10:18
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

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/JAN/2021 10:39
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

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) **30 Jan 2021 16:53:32**

Generated On: 09 Jun 2021 14:54:17

SAEID	USA-US032-2020-MRNA-1273-P30 1000003
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/JAN/2021 12:28
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

US3032277 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032277

Form: Participant Creation

Generated On: 09 Jun 2021 14:54:17

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		14 Apr 2021 15:20:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'US3032277'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:49:33

US3032277
Form: Participant Creation
Generated On: 09 Jun 2021 14:54:17

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:24

FDA-CBER-2022-1614-0166007

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:49:34

US3032277
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:24

US3032277
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:54:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'SCRN'	System	21 Aug 2020 00:47:24

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '(b) (6) 1929'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:49:35

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '90'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'YEARS'	System	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '90'	System	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Male (M)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:54:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:17
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:36

US3032277
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:17

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:17

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Aug 2020'	System	20 Aug 2020 22:17:49

US3032277
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:17
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2020'	System	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:17

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Amendment 2 (2)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:49

US3032277
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:17

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:49

US3032277
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:17
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:17

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:54:17

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:49:34

US3032277
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:17

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '1'	System	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:54:17

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:38
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:17:37

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:52:46

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
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)	21 Aug 2020 00:56:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:56:25
Data point term sent to Coder	System	21 Aug 2020 00:56:09
User entered 'hypertension'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:16:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2010'	System	21 Aug 2020 00:55:39

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2010'	System	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:55:39

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
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)	21 Aug 2020 00:56:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:56:25
Data point term sent to Coder	System	21 Aug 2020 00:56:10
User entered 'diabetes mellitus type 2'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:55

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2005'	System	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2005'	System	21 Aug 2020 00:55:55

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:55:55

US3032277
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:55:55

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 00:58:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:58:28
Data point term sent to Coder	System	21 Aug 2020 00:57:13
User entered 'hypercholesterolemia'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:18

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:18

US3032277
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:48:47
DataPoint Verified.		3 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2010'	System	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2010'	System	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:54:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:56:18

US3032277
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:56:18

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:58:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:58:28
Data point term sent to Coder	System	21 Aug 2020 00:57:11
User entered 'enlarged prostate'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:48:47
DataPoint Verified.		3 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2005'	System	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2005'	System	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:54:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:56:50

US3032277
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:56:50

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal failure, LLT: Kidney failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:58:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:58:28
Data point term sent to Coder	System	21 Aug 2020 00:57:13
User entered 'kidney failure'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2005'	System	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2005'	System	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:57:03

US3032277

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 00:59:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Aug 2020 00:59:29
Data point term sent to Coder	System	21 Aug 2020 00:58:14
User entered 'anemia'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 1989'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:48

US3032277

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:48

US3032277
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:48

FDA-CBER-2022-1614-0166092

US3032277
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:57:48

US3032277

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 1989'	System	21 Aug 2020 00:57:48

US3032277

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '1989'	System	21 Aug 2020 00:57:48

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:57:48

US3032277

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:57:48

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 19:28:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 19:28:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Data point term sent to Coder	System	01 Oct 2020 18:16:17
Coding entries removed.	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:15:45
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:15:45
User entered 'Capoten ALLERGY' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:15:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:17
Data point term sent to Coder	System	21 Aug 2020 00:59:17
User entered 'capatin allergy'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 1982'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:42

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 1982'	System	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '1982'	System	21 Aug 2020 00:58:42

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:58:42

FDA-CBER-2022-1614-0166106

US3032277

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:58:42

US3032277

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 01:00:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Aug 2020 01:00:30
Data point term sent to Coder	System	21 Aug 2020 00:59:19
User entered 'benign prostatic hyperplasia'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:58

US3032277

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:58

US3032277

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:58

US3032277

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:58

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:58

FDA-CBER-2022-1614-0166112

US3032277

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:58:58

US3032277

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2005'	System	21 Aug 2020 00:58:58

US3032277
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2005'	System	21 Aug 2020 00:58:58

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:58:58

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:58:58

US3032277
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:52:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:47:37
Data point term sent to Coder	System	11 Nov 2020 17:46:40
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:45:48
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:45:48
User entered 'GOUT bilateral feet' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:45:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 04:53:59
Query 'Per DM CLR: Please specify the location of GOUT. Review and update Med History eCRF as appropriate. ' answered with 'UNKNOWN PER SUBECT' (Site from DM).		14 Sep 2020 23:24:26
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update Med History eCRF as appropriate. ' (Site from DM).		09 Sep 2020 00:17:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 01:00:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 01:00:30
Data point term sent to Coder	System	21 Aug 2020 00:59:19
User entered 'gout'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2019'	System	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2019'	System	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:59:18

US3032277

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 00:59:18

US3032277
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:39:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:39:24
User closed query 'Per DM CLR: Please specify the location of BLOOD CLOT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:04:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Data point term sent to Coder	System	01 Oct 2020 22:41:23
Query 'Per DM CLR: Please specify the location of BLOOD CLOT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	01 Oct 2020 22:40:50
Coding entries removed.	Samantha Wieseler (b) (4) (b) (4)	01 Oct 2020 22:40:30
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	01 Oct 2020 22:40:30
User entered 'BLOOD CLOT-Right lower leg' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	01 Oct 2020 22:40:30
User opened query 'Per DM CLR: Please specify the location of BLOOD CLOT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:57:11
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 23:25:45

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 23:25:45
Data point term sent to Coder	System	14 Sep 2020 23:25:05
User entered 'BLOOD CLOT'	(b) (4), (b) (6)	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:24:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2013'	System	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2013'	System	14 Sep 2020 23:24:55

Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 2013'	System	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '2013'	System	14 Sep 2020 23:24:55

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:13:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:13:11
Data point term sent to Coder	System	25 Nov 2020 15:11:57
User entered 'seasonal allergies'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:11:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'UN UNK 1995'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:11:46

FDA-CBER-2022-1614-0166140

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '0'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:11:46

US3032277
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:11:46

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:11:46

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:07:49
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '0'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:11:46

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'Jan 1995'	System	25 Nov 2020 15:11:46

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '1995'	System	25 Nov 2020 15:11:46

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	25 Nov 2020 15:11:46

US3032277

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:54:17

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	25 Nov 2020 15:11:46

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.		13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

US3032277

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '15:30'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

US3032277

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:17

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '20 Aug 2020 15:30'	System	21 Aug 2020 00:53:29

US3032277

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:17

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '168.9' cm	Kelsey Kelley (b) (4)	21 Aug 2020 00:53:29
DataPoint set to visible.	System	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:17

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '59.9' kg	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29
DataPoint set to visible.	System	20 Aug 2020 22:17:49

FDA-CBER-2022-1614-0166154

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
Amendment Manager: User entered '20.99750'	System	17 Sep 2020 00:17:12
User entered '21.0'	System	21 Aug 2020 00:53:29
DataPoint set to visible.	System	20 Aug 2020 22:17:49

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'kg/m2'	System	21 Aug 2020 00:53:29
DataPoint set to visible.	System	20 Aug 2020 22:17:49

US3032277

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:17

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
User closed query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:52:58
Query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:34
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User opened query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:05:27
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '36.6' C	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

FDA-CBER-2022-1614-0166157

US3032277

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:54:17

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:47:19
User closed query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:53:00
Query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:39
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User opened query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:05:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '68'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'bpm'	System	21 Aug 2020 00:53:29

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '16'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'breaths/min'	System	21 Aug 2020 00:53:29

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '154'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'mmHg'	System	21 Aug 2020 00:53:29

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:26:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '82'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:53:29

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'mmHg'	System	21 Aug 2020 00:53:29

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47

US3032277
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47

Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:45

US3032277

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:17

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:45

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:17
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'grocery shopping and out with friends, wears mask 50% of the time'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:17
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:09:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:51:29

US3032277

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:35
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	20 Aug 2020 22:18:13
	(b) (4)	

US3032277

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:13

US3032277

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:13

US3032277
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:54:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'VISIT1'	System	20 Aug 2020 22:18:13

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:34:12

US3032277
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:17

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:03:26
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:03:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 21:34:12
User entered '187442' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:34:12

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:17

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:34:12

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:46:51

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 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:46:51

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:46:51

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:46:51

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:17

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:46:51

US3032277

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:17

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:20:13
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:40:05
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	29 Oct 2020 21:31:11
User entered 'No (N)'	Linden DeBoer (b) (4)	29 Oct 2020 21:31:06
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:17:15
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:52:23

FDA-CBER-2022-1614-0166205

US3032277
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:47:19
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:53:11
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:57
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:05:59
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '168.9' cm	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '59.9' kg	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:53:11
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:57
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:05:59
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '168.9' cm	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4)	06 Oct 2020 14:28:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Oct 2020 14:28:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:35
User entered '59.9' kg	Kelsey Kelley (b) (4)	21 Aug 2020 00:54:44

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '15:30'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '20 Aug 2020 15:30'	System	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '36.6' C	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '68'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'bpm'	System	21 Aug 2020 00:54:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '16'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'breaths/min'	System	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:13:28
User entered '126' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:13:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '154'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'mmHg'	System	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:54:17

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:13:28
User entered '80' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:13:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '82'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

FDA-CBER-2022-1614-0166224

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'mmHg'	System	21 Aug 2020 00:54:44

US3032277
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:47:19
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:53:11
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:57
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:05:59
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '168.9' cm	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:54:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:47:19
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:28:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '59.9' kg	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:54:44

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:28
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	21 Aug 2020 00:55:10
User entered '17:58'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '20 Aug 2020 17:58'	System	21 Aug 2020 00:55:10

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:17

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '36.7' C	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '80'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'bpm'	System	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '16'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'breaths/min'	System	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '136'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'mmHg'	System	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:54:17

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:35
User entered '89'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:55:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'mmHg'	System	21 Aug 2020 00:55:10

US3032277

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:03

US3032277

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:54:17

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:47:03

US3032277
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:17

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:03

US3032277
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:17
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:03

US3032277

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:17

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 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:03

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 22:18:03

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:03

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:17

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '17:08'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:03

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:17

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '20 Aug 2020 17:08'	System	20 Aug 2020 22:18:03

US3032277

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4) (b) (4)	20 Aug 2020 22:18:03

US3032277

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:17

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'ONCE'	System	20 Aug 2020 22:18:03

US3032277

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 22:18:03

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:47

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:47

US3032277

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:17

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '16:23'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:59:47

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:54:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '20 Aug 2020 16:23'	System	21 Aug 2020 00:59:47

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '20 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

FDA-CBER-2022-1614-0166260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:17

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:17

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '16:07'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

FDA-CBER-2022-1614-0166263

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:54:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '20 Aug 2020 16:07'	System	21 Aug 2020 01:00:03

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:17

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:17

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:17

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:03

US3032277

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:54:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	21 Aug 2020 01:00:03

US3032277

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 01:00:10

US3032277

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:54:17

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '1'	System	21 Aug 2020 01:00:10

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:55:25', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '218afc6e-8853-43a1-873d-001678f4915e'	System	20 Aug 2020 22:56:35
User entered 'Yes (Y)'	System	20 Aug 2020 22:56:35

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:55:47', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '218afc6e-8853-43a1-873d-001678f4915e'	System	20 Aug 2020 22:56:35
User entered '97.4'	System	20 Aug 2020 22:56:35

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:55:53', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '218afc6e-8853-43a1-873d-001678f4915e'	System	20 Aug 2020 22:56:35
User entered 'No (N)'	System	20 Aug 2020 22:56:35

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:56:27', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '218afc6e-8853-43a1-873d-001678f4915e'	System	20 Aug 2020 22:56:35
User entered '20 Aug 2020 17:56'	System	20 Aug 2020 22:56:35

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 17:28'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 19:58'	System	20 Aug 2020 22:18:03

FDA-CBER-2022-1614-0166277

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:18:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:17
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 20:53'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 2'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:53:48', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '8f75d863-8da3-46c8-b77e-c232a57777c0'	System	21 Aug 2020 21:54:29
User entered 'Yes (Y)'	System	21 Aug 2020 21:54:29

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:53:59', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '8f75d863-8da3-46c8-b77e-c232a57777c0'	System	21 Aug 2020 21:54:29
User entered '97.5'	System	21 Aug 2020 21:54:29

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:54:05', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '8f75d863-8da3-46c8-b77e-c232a57777c0'	System	21 Aug 2020 21:54:29
User entered 'No (N)'	System	21 Aug 2020 21:54:29

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:54:25', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '8f75d863-8da3-46c8-b77e-c232a57777c0'	System	21 Aug 2020 21:54:29
User entered '21 Aug 2020 16:54'	System	21 Aug 2020 21:54:29

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

FDA-CBER-2022-1614-0166293

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 3'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:43:49', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '87d7d640-70a4-4a59-9136-fc360e8164a5'	System	22 Aug 2020 21:44:49
User entered 'Yes (Y)'	System	22 Aug 2020 21:44:49

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:43:59', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '87d7d640-70a4-4a59-9136-fc360e8164a5'	System	22 Aug 2020 21:44:49
User entered '97.5'	System	22 Aug 2020 21:44:49

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:44:05', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '87d7d640-70a4-4a59-9136-fc360e8164a5'	System	22 Aug 2020 21:44:49
User entered 'No (N)'	System	22 Aug 2020 21:44:49

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:44:48', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '87d7d640-70a4-4a59-9136-fc360e8164a5'	System	22 Aug 2020 21:44:49
User entered '22 Aug 2020 16:44'	System	22 Aug 2020 21:44:49

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 4'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:00', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'dd3b57b3-88ea-4685-a7c2-3284e97d7f7d'	System	23 Aug 2020 22:07:34
User entered 'Yes (Y)'	System	23 Aug 2020 22:07:34

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:14', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'dd3b57b3-88ea-4685-a7c2-3284e97d7f7d'	System	23 Aug 2020 22:07:34
User entered '97.8'	System	23 Aug 2020 22:07:34

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:20', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'dd3b57b3-88ea-4685-a7c2-3284e97d7f7d'	System	23 Aug 2020 22:07:34
User entered 'No (N)'	System	23 Aug 2020 22:07:34

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:31', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'dd3b57b3-88ea-4685-a7c2-3284e97d7f7d'	System	23 Aug 2020 22:07:34
User entered '23 Aug 2020 17:07'	System	23 Aug 2020 22:07:34

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 5'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:02:29', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'e3a5ab62-b24e-4b39-9725-c4c62cb84d36'	System	24 Aug 2020 22:03:05
User entered 'Yes (Y)'	System	24 Aug 2020 22:03:05

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:02:41', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'e3a5ab62-b24e-4b39-9725-c4c62cb84d36'	System	24 Aug 2020 22:03:05
User entered '98.5'	System	24 Aug 2020 22:03:05

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:02:48', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'e3a5ab62-b24e-4b39-9725-c4c62cb84d36'	System	24 Aug 2020 22:03:05
User entered 'No (N)'	System	24 Aug 2020 22:03:05

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:01', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'e3a5ab62-b24e-4b39-9725-c4c62cb84d36'	System	24 Aug 2020 22:03:05
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 22:03:05

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 6'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:15:30', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '1c9fc239-bf45-4af5-98dd-9826ffbb1641'	System	26 Aug 2020 00:16:01
User entered 'Yes (Y)'	System	26 Aug 2020 00:16:01

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:15:43', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '1c9fc239-bf45-4af5-98dd-9826ffbb1641'	System	26 Aug 2020 00:16:01
User entered '97.5'	System	26 Aug 2020 00:16:01

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:15:48', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '1c9fc239-bf45-4af5-98dd-9826ffbb1641'	System	26 Aug 2020 00:16:01
User entered 'No (N)'	System	26 Aug 2020 00:16:01

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:15:58', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '1c9fc239-bf45-4af5-98dd-9826ffbb1641'	System	26 Aug 2020 00:16:01
User entered '25 Aug 2020 19:15'	System	26 Aug 2020 00:16:01

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 7'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:00', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '31adfd85-a637-4659-944f-6836c2ea820e'	System	26 Aug 2020 22:53:31
User entered 'Yes (Y)'	System	26 Aug 2020 22:53:31

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:11', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '31adfd85-a637-4659-944f-6836c2ea820e'	System	26 Aug 2020 22:53:31
User entered '98.1'	System	26 Aug 2020 22:53:31

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:18', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '31adfd85-a637-4659-944f-6836c2ea820e'	System	26 Aug 2020 22:53:31
User entered 'No (N)'	System	26 Aug 2020 22:53:31

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:29', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '31adfd85-a637-4659-944f-6836c2ea820e'	System	26 Aug 2020 22:53:31
User entered '26 Aug 2020 17:53'	System	26 Aug 2020 22:53:31

US3032277
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:57:08', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '03e61036-3f08-468d-95bd-f56a3b8ca00c'	System	20 Aug 2020 22:58:46
User entered 'None (1)'	System	20 Aug 2020 22:58:46

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:57:50', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '03e61036-3f08-468d-95bd-f56a3b8ca00c'	System	20 Aug 2020 22:58:46
User entered 'No (N)'	System	20 Aug 2020 22:58:46

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:57:58', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '03e61036-3f08-468d-95bd-f56a3b8ca00c'	System	20 Aug 2020 22:58:46
User entered 'No (N)'	System	20 Aug 2020 22:58:46

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:58:15', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '03e61036-3f08-468d-95bd-f56a3b8ca00c'	System	20 Aug 2020 22:58:46
User entered 'None (1)'	System	20 Aug 2020 22:58:46

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:58:41', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '03e61036-3f08-468d-95bd-f56a3b8ca00c'	System	20 Aug 2020 22:58:46
User entered '20 Aug 2020 17:58'	System	20 Aug 2020 22:58:46

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 17:28'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 19:58'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 20:53'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 2'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:54:44', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4ed4f721-5686-415f-bac2-f86043f2c276'	System	21 Aug 2020 21:55:17
User entered 'None (1)'	System	21 Aug 2020 21:55:17

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:54:48', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4ed4f721-5686-415f-bac2-f86043f2c276'	System	21 Aug 2020 21:55:17
User entered 'No (N)'	System	21 Aug 2020 21:55:17

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:54:53', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4ed4f721-5686-415f-bac2-f86043f2c276'	System	21 Aug 2020 21:55:17
User entered 'No (N)'	System	21 Aug 2020 21:55:17

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:00', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4ed4f721-5686-415f-bac2-f86043f2c276'	System	21 Aug 2020 21:55:17
User entered 'None (1)'	System	21 Aug 2020 21:55:17

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:16', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4ed4f721-5686-415f-bac2-f86043f2c276'	System	21 Aug 2020 21:55:17
User entered '21 Aug 2020 16:55'	System	21 Aug 2020 21:55:17

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 3'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:45:14', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '21a9afe7-fe36-459b-8ff4-5669eaba2f94'	System	22 Aug 2020 21:46:12
User entered 'None (1)'	System	22 Aug 2020 21:46:12

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:45:20', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '21a9afe7-fe36-459b-8ff4-5669eaba2f94'	System	22 Aug 2020 21:46:12
User entered 'No (N)'	System	22 Aug 2020 21:46:12

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:45:31', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '21a9afe7-fe36-459b-8ff4-5669eaba2f94'	System	22 Aug 2020 21:46:12
User entered 'No (N)'	System	22 Aug 2020 21:46:12

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:45:46', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '21a9afe7-fe36-459b-8ff4-5669eaba2f94'	System	22 Aug 2020 21:46:12
User entered 'None (1)'	System	22 Aug 2020 21:46:12

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:46:09', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '21a9afe7-fe36-459b-8ff4-5669eaba2f94'	System	22 Aug 2020 21:46:12
User entered '22 Aug 2020 16:46'	System	22 Aug 2020 21:46:12

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 4'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:40', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '95384520-584c-4986-ba8d-9d4a7ec8244e'	System	23 Aug 2020 22:08:13
User entered 'None (1)'	System	23 Aug 2020 22:08:13

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:45', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '95384520-584c-4986-ba8d-9d4a7ec8244e'	System	23 Aug 2020 22:08:13
User entered 'No (N)'	System	23 Aug 2020 22:08:13

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:50', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '95384520-584c-4986-ba8d-9d4a7ec8244e'	System	23 Aug 2020 22:08:13
User entered 'No (N)'	System	23 Aug 2020 22:08:13

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:07:56', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '95384520-584c-4986-ba8d-9d4a7ec8244e'	System	23 Aug 2020 22:08:13
User entered 'None (1)'	System	23 Aug 2020 22:08:13

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:08:12', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '95384520-584c-4986-ba8d-9d4a7ec8244e'	System	23 Aug 2020 22:08:13
User entered '23 Aug 2020 17:08'	System	23 Aug 2020 22:08:13

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 5'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:12', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '0efe3111-b6d8-42fc-b61f-dab93fa8911b'	System	24 Aug 2020 22:03:47
User entered 'None (1)'	System	24 Aug 2020 22:03:47

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:17', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '0efe3111-b6d8-42fc-b61f-dab93fa8911b'	System	24 Aug 2020 22:03:47
User entered 'No (N)'	System	24 Aug 2020 22:03:47

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:21', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '0efe3111-b6d8-42fc-b61f-dab93fa8911b'	System	24 Aug 2020 22:03:47
User entered 'No (N)'	System	24 Aug 2020 22:03:47

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:31', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '0efe3111-b6d8-42fc-b61f-dab93fa8911b'	System	24 Aug 2020 22:03:47
User entered 'None (1)'	System	24 Aug 2020 22:03:47

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:43', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '0efe3111-b6d8-42fc-b61f-dab93fa8911b'	System	24 Aug 2020 22:03:47
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 22:03:47

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 6'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:05', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'aa38a066-ac9d-4953-bc27-4f4e30549dd8'	System	26 Aug 2020 00:16:35
User entered 'None (1)'	System	26 Aug 2020 00:16:35

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:10', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'aa38a066-ac9d-4953-bc27-4f4e30549dd8'	System	26 Aug 2020 00:16:35
User entered 'No (N)'	System	26 Aug 2020 00:16:35

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:14', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'aa38a066-ac9d-4953-bc27-4f4e30549dd8'	System	26 Aug 2020 00:16:35
User entered 'No (N)'	System	26 Aug 2020 00:16:35

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:20', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'aa38a066-ac9d-4953-bc27-4f4e30549dd8'	System	26 Aug 2020 00:16:35
User entered 'None (1)'	System	26 Aug 2020 00:16:35

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:30', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'aa38a066-ac9d-4953-bc27-4f4e30549dd8'	System	26 Aug 2020 00:16:35
User entered '25 Aug 2020 19:16'	System	26 Aug 2020 00:16:35

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 7'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:40', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4f682dde-6932-4a9b-861e-4a6128e6c293'	System	26 Aug 2020 22:54:09
User entered 'None (1)'	System	26 Aug 2020 22:54:09

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:45', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4f682dde-6932-4a9b-861e-4a6128e6c293'	System	26 Aug 2020 22:54:09
User entered 'No (N)'	System	26 Aug 2020 22:54:09

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:50', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4f682dde-6932-4a9b-861e-4a6128e6c293'	System	26 Aug 2020 22:54:09
User entered 'No (N)'	System	26 Aug 2020 22:54:09

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:53:57', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4f682dde-6932-4a9b-861e-4a6128e6c293'	System	26 Aug 2020 22:54:09
User entered 'None (1)'	System	26 Aug 2020 22:54:09

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:06', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '4f682dde-6932-4a9b-861e-4a6128e6c293'	System	26 Aug 2020 22:54:09
User entered '26 Aug 2020 17:54'	System	26 Aug 2020 22:54:09

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:59:35', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'None (0)'	System	20 Aug 2020 23:00:28

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:59:39', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'None (0)'	System	20 Aug 2020 23:00:28

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:59:46', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'None (0)'	System	20 Aug 2020 23:00:28

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:59:50', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'None (0)'	System	20 Aug 2020 23:00:28

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T17:59:55', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'None (0)'	System	20 Aug 2020 23:00:28

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T18:00:01', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'None (0)'	System	20 Aug 2020 23:00:28

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T18:00:09', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered 'No (N)'	System	20 Aug 2020 23:00:28

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-20T18:00:25', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '109333a7-d2eb-47fd-93ef-055bdf389614'	System	20 Aug 2020 23:00:28
User entered '20 Aug 2020 18:00'	System	20 Aug 2020 23:00:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 17:28'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 19:58'	System	20 Aug 2020 22:18:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '20 Aug 2020 20:53'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 2'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:33', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'None (0)'	System	21 Aug 2020 21:56:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:40', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'None (0)'	System	21 Aug 2020 21:56:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:44', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'None (0)'	System	21 Aug 2020 21:56:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:47', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'None (0)'	System	21 Aug 2020 21:56:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:50', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'None (0)'	System	21 Aug 2020 21:56:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:55:53', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'None (0)'	System	21 Aug 2020 21:56:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:56:00', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered 'No (N)'	System	21 Aug 2020 21:56:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-21T16:56:18', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '08308e8b-ab1f-4801-931e-96bbac7794d8'	System	21 Aug 2020 21:56:20
User entered '21 Aug 2020 16:56'	System	21 Aug 2020 21:56:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 3'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:46:32', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'None (0)'	System	22 Aug 2020 21:47:56

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:46:39', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'None (0)'	System	22 Aug 2020 21:47:56

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:46:45', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'None (0)'	System	22 Aug 2020 21:47:56

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:46:53', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'None (0)'	System	22 Aug 2020 21:47:56

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:46:59', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'None (0)'	System	22 Aug 2020 21:47:56

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:47:05', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'None (0)'	System	22 Aug 2020 21:47:56

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:47:19', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered 'No (N)'	System	22 Aug 2020 21:47:56

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-22T16:47:54', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'ca0bef88-2f4b-417d-8bdb-623cbb8af65c'	System	22 Aug 2020 21:47:56
User entered '22 Aug 2020 16:47'	System	22 Aug 2020 21:47:56

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 4'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:08:32', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'None (0)'	System	23 Aug 2020 22:09:49

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:08:45', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'No interference with activity (1)'	System	23 Aug 2020 22:09:49

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:08:51', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'None (0)'	System	23 Aug 2020 22:09:49

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:08:58', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'None (0)'	System	23 Aug 2020 22:09:49

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:09:08', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'None (0)'	System	23 Aug 2020 22:09:49

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:09:19', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'None (0)'	System	23 Aug 2020 22:09:49

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:09:27', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered 'No (N)'	System	23 Aug 2020 22:09:49

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-23T17:09:47', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '53174001-9ffc-4307-9c54-0605b5952904'	System	23 Aug 2020 22:09:49
User entered '23 Aug 2020 17:09'	System	23 Aug 2020 22:09:49

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 5'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:03:59', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'None (0)'	System	24 Aug 2020 22:05:19

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:04:17', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'No interference with activity (1)'	System	24 Aug 2020 22:05:19

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:04:23', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'None (0)'	System	24 Aug 2020 22:05:19

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:04:29', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'None (0)'	System	24 Aug 2020 22:05:19

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:04:34', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'None (0)'	System	24 Aug 2020 22:05:19

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:04:39', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'None (0)'	System	24 Aug 2020 22:05:19

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:04:47', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered 'No (N)'	System	24 Aug 2020 22:05:19

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-24T17:05:14', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '72f94b2e-dc90-417e-93f5-5a7a90575b70'	System	24 Aug 2020 22:05:19
User entered '24 Aug 2020 17:05'	System	24 Aug 2020 22:05:19

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

FDA-CBER-2022-1614-0166460

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 6'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:39', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'None (0)'	System	26 Aug 2020 00:17:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:42', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'None (0)'	System	26 Aug 2020 00:17:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:45', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'None (0)'	System	26 Aug 2020 00:17:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:49', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'None (0)'	System	26 Aug 2020 00:17:20

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:51', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'None (0)'	System	26 Aug 2020 00:17:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:16:54', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'None (0)'	System	26 Aug 2020 00:17:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:17:04', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered 'No (N)'	System	26 Aug 2020 00:17:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-25T19:17:15', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: '89c43797-3c94-4ed7-bf15-87500ccea6c7'	System	26 Aug 2020 00:17:20
User entered '25 Aug 2020 19:17'	System	26 Aug 2020 00:17:20

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
Data entry locked.	System	20 Aug 2020 22:18:03
User entered 'Day 7'	System	20 Aug 2020 22:18:03

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:17', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'None (0)'	System	26 Aug 2020 22:55:05

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:22', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'None (0)'	System	26 Aug 2020 22:55:05

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:29', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'None (0)'	System	26 Aug 2020 22:55:05

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:35', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'None (0)'	System	26 Aug 2020 22:55:05

US3032277
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:40', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'None (0)'	System	26 Aug 2020 22:55:05

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:43', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'None (0)'	System	26 Aug 2020 22:55:05

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

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)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:54:50', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered 'No (N)'	System	26 Aug 2020 22:55:05

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C07DB1E3-8A49-42C6-AABF-981DF073E26B)', Time: '2020-08-26T17:55:01', User OID: 'PatientReportedOutcome (US3032277)', ODM File OID: 'cfcbfae2-e5cf-441c-a5e7-359eadc6bf8d'	System	26 Aug 2020 22:55:05
User entered '26 Aug 2020 17:55'	System	26 Aug 2020 22:55:05

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 22:18:03

US3032277

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:07:53
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 22:18:03

US3032277

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:17

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:15:22

US3032277

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '27 Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 21:15:22

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 21:15:22

FDA-CBER-2022-1614-0166485

US3032277

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:17

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:15:22

US3032277

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:15:30

US3032277

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:17

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered '1'	System	10 Sep 2020 21:15:30

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:15:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '03 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:15:52

Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:15:52

US3032277

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:17

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:15:52

Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:16:43

US3032277

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:17

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	10 Sep 2020 21:16:43

US3032277
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:17

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:16:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:16:55

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:16:55

US3032277

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:54:17

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:16:55

US3032277

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User closed query 'Per CDM, re-query: If the subject is not continuing to the next visit, then please update this field accordingly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:26:37
Query 'Per CDM, re-query: If the subject is not continuing to the next visit, then please update this field accordingly, else clarify. Thank you. ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 19:32:49
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 19:32:41
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 19:32:41
User opened query 'Per CDM, re-query: If the subject is not continuing to the next visit, then please update this field accordingly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:53:38
User closed query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. If Visit 2 Day 29 occurred, then complete the forms in Visit 2 Day 29 folder as appropriate. Else, update this field accordingly. Thank you.' (Site from DM).		18 Nov 2020 04:10:42
Query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. If Visit 2 Day 29 occurred, then complete the forms in Visit 2 Day 29 folder as appropriate. Else, update this field accordingly. Thank you.' answered with 'Subject is a lost to follow' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 15:57:59
User opened query 'Per CDM: Is the participant continuing to the next visit? = Yes; however, End of study form is completed. If Visit 2 Day 29 occurred, then complete the forms in Visit 2 Day 29 folder as appropriate. Else, update this field accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:11:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25

US3032277
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:17

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:17:05

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:47
User entered empty.	System	02 Dec 2020 19:32:41
User entered '1'	System	10 Sep 2020 21:17:05

US3032277

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

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User closed query 'Per CDM: please confirm if OL-D1 occurred. If no, please remove data from CRF so that the form may be inactivated, or otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 05:59:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:06:03
Query 'Per CDM: please confirm if OL-D1 occurred. If no, please remove data from CRF so that the form may be inactivated, or otherwise clarify.' answered with 'subject did not come in due to early withdrawl' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	13 Apr 2021 14:07:07
User opened query 'Per CDM: please confirm if OL-D1 occurred. If no, please remove data from CRF so that the form may be inactivated, or otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 23:41:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:28:20
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	16 Mar 2021 13:47:56

US3032277

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

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:06:03
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:28:20
User entered empty.	Linden DeBoer (b) (4) (b) (4)	16 Mar 2021 13:47:56

US3032277

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

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

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 19:48:35
DataPoint Verified.		13 Apr 2021 16:06:03
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:28:20
User entered empty.	Linden DeBoer (b) (4) (b) (4)	16 Mar 2021 13:47:56

US3032277

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

Form: Visit Date

Generated On: 09 Jun 2021 14:54:17

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered 'UNBLND_DECIDE'	System	16 Mar 2021 13:47:56

US3032277

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:54:17

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:27:43

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:05:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:44:55
User entered 'USA-US032-2020-mRNA-1273-P301000003'	System	15 Sep 2020 15:44:51
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 15:44:51

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer haemorrhage, LLT: Acute duodenal ulcer with hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 20:32:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 20:32:09
Data point term sent to Coder	System	14 Sep 2020 20:31:25
User entered 'Acute Duodenal ulcer with hemorrhage'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '12 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
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	14 Sep 2020 20:31:27
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:27
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	14 Sep 2020 20:31:03
User entered '10:00'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	14 Sep 2020 20:31:27
User entered '12 Sep 2020 10:00'	System	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 14:07:34
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:07:34
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:07:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 14:07:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:32:39
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	28 Jan 2021 15:57:17
User entered '17 Sep 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	28 Jan 2021 15:57:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:46:32
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:46:32
User entered '14 Sep 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:46:32
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Nov 2020 14:07:19
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Nov 2020 14:07:19
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:07:19
User entered '17 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:07:19
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Nov 2020 14:06:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:32:39
User entered '14 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is received.' canceled (Site from Safety).		19 Oct 2020 16:41:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is received.' (Site from Safety).		19 Oct 2020 16:40:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 20:31:27
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 20:31:03
User entered '07:00'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		20 Nov 2020 17:41:27
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		24 Sep 2020 14:35:21
User entered empty.	System	14 Sep 2020 20:31:27
User entered '14 Sep 2020 07:00'	System	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:13:27
User closed query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' (Site from Safety).		20 Nov 2020 15:31:26
Query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 22:13:37
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 22:13:28
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 22:13:28
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 22:13:28
User opened query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:14:19
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 03:19:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'there is an admission date. subject still in hospital so D/C date is yet to be determined' (Site from System).	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:32:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 20:31:03
User entered '1'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:36
DataPoint Un-verified.	Linden DeBoer (b) (4)	25 Nov 2020 14:58:19
User entered '12 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 14:58:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:13:10
User closed query 'PV Query: Please clarify hospital admission date as narrative has 13 Sep and date of hospital admission field is listed as 12 Sep 2020.' (Site from Safety).		20 Nov 2020 15:31:12
Query 'PV Query: Please clarify hospital admission date as narrative has 13 Sep and date of hospital admission field is listed as 12 Sep 2020.' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4)	19 Nov 2020 18:24:58
DataPoint Un-verified.	Linden DeBoer (b) (4)	19 Nov 2020 18:24:19
Signature has been broken.	Linden DeBoer (b) (4)	19 Nov 2020 18:24:19
User entered '13 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	19 Nov 2020 18:24:19
User opened query 'PV Query: Please clarify hospital admission date as narrative has 13 Sep and date of hospital admission field is listed as 12 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:14:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:05:32
User entered '12 Sep 2020'	Linden DeBoer (b) (4)	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 13:55:19
User entered '17 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 13:55:19
User closed query 'PV Query: Discharge date was reported as 14 Sep 2020. Event details reported planned discharge date of 15 Sep 2020. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 23:38:56
Query 'PV Query: Discharge date was reported as 14 Sep 2020. Event details reported planned discharge date of 15 Sep 2020. Please reconcile.' answered with 'DISCHARGE DATE CORRECT OF 14-SEP-2020' (Site from Safety).	Russell Herstein (b) (4) (b) (4)	21 Oct 2020 02:21:41
User opened query 'PV Query: Discharge date was reported as 14 Sep 2020. Event details reported planned discharge date of 15 Sep 2020. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:41:09
User closed query 'PV Query: Discharge date was reported as 14 Sep 2020. Event details reported planned discharge date of 15 Sep 2020. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:55:53
Query 'PV Query: Discharge date was reported as 14 Sep 2020. Event details reported planned discharge date of 15 Sep 2020. Please reconcile.' answered with 'still waiting on medical records to have correct data' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:10:47
User opened query 'PV Query: Discharge date was reported as 14 Sep 2020. Event details reported planned discharge date of 15 Sep 2020. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:11:31
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		02 Oct 2020 12:08:27
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:12:57
User entered '14 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:12:35
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 14:34:54
User entered empty.	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
User closed query 'PV Query: Please provide causality assessment (relationship to study drug and study procedure). Please update response as either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:55:59
Query 'PV Query: Please provide causality assessment (relationship to study drug and study procedure). Please update response as either Related or Not related.' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:11:52
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:11:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:11:44
User opened query 'PV Query: Please provide causality assessment (relationship to study drug and study procedure). Please update response as either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:13:03
Query 'PV Query: Please provide causality assessment for the event. Please update response as either Related or Not related.' canceled (Site from Safety).		08 Oct 2020 18:12:58
User opened query 'PV Query: Please provide causality assessment for the event. Please update response as either Related or Not related.' (Site from Safety).		08 Oct 2020 18:12:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Query 'Per CDM SAE RECON: it appears that 'Not Related' is recorded for both Relationship to IP and Study Procedure in Safety Database. Please review, reconcile, and update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:39:21

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Relationship to investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM SAE RECON: it appears that 'Not Related' is recorded for both Relationship to IP and Study Procedure in Safety Database. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:48:14
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:11:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:11:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:15:55
User closed query 'Per CDM; it appears this has not been updated to 'Not Applicable' from 'IP Withdrawn' yet IP discontinuation and end of study are recorded as SAE. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:46:52
DataPoint Un-verified.		24 Nov 2020 23:16:50
DataPoint Verified.		24 Nov 2020 23:16:11
Query 'Per CDM; it appears this has not been updated to 'Not Applicable' from 'IP Withdrawn' yet IP discontinuation and end of study are recorded as SAE. Please reconcile.' answered with 'CHANGED TO NOT APPLICABLE' (Site from DM).	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:39:18
User opened query 'Per CDM; it appears this has not been updated to 'Not Applicable' from 'IP Withdrawn' yet IP discontinuation and end of study are recorded as SAE. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:26:51
User closed query 'Per CDM : Please note in the AE page Action taken with investigational product is IP withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile with AE and dosing/End of study pages. Thank you.' (Site from DM).		22 Nov 2020 22:26:51
Query 'Per CDM : Please note in the AE page Action taken with investigational product is IP withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile with AE and dosing/End of study pages. Thank you.' answered with 'data udapaed' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 22:14:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 22:14:18

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM : Please note in the AE page Action taken with investigational product is IP withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile with AE and dosing/End of study pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:31:47
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation and/or End of Study/Study Discontinuation record to match this information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:31:47
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 04:54:51
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'data updated' (Site from System).	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:57:01
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation and/or End of Study/Study Discontinuation record to match this information. Please update applicable details as appropriate. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:56:43
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Nov 2020 20:39:47
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:39:47
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Nov 2020 20:39:47

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 15:03:19
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 15:03:19
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation and/or End of Study/Study Discontinuation record to match this information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 22:50:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:15:15
User entered 'None (NONE)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User closed query 'Per CDM, per DM CLR re-query: Please review and ensure that Con Med/Con Proc for this serious condition is added in the appropriate eCRFs, else provide comment for no treatment given. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 04:19:23
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	25 Nov 2020 14:55:42
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:42
User entered '0' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:42
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	25 Nov 2020 14:55:12
Query 'Per CDM, per DM CLR re-query: Please review and ensure that Con Med/Con Proc for this serious condition is added in the appropriate eCRFs, else provide comment for no treatment given. Thank you. ' answered with 'update' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:54:54
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 23:21:21
DataPoint Verified.		09 Nov 2020 18:14:00
User opened query 'Per CDM, per DM CLR re-query Please review and ensure that Con Med/Con Proc for this serious condition is added in the appropriate eCRFs, else provide comment for no treatment given Thank you. ' (Site from DM).		09 Nov 2020 08:09:44
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).		09 Nov 2020 08:09:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'waiting on medical records' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:14:59
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 21:07:12
User entered '1'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		19 Jan 2021 11:54:19
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'subject was administered medication at hospital. awaiting medical release to know what was administered. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 15:41:24
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 03:34:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:42
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:42
User entered '1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:12
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:12
User entered '1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:12
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:14:00
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).		06 Nov 2020 15:11:44
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 15:01:49
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:06:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:06:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 11:51:45
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		22 Oct 2020 23:38:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AWAITING MED RECORDS' (Site from Safety).	Russell Herstein (b) (4) (b) (4)	21 Oct 2020 02:22:04
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:40:18

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Outcome

Audit	User	Time (GMT)
Query '*REQUERY* PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:38:42
User opened query '*REQUERY* PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		19 Oct 2020 16:38:30
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).		12 Oct 2020 13:56:08
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'waiting for medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:12:01
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:09:50
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		02 Oct 2020 12:08:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'waiting for medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:14:46

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 14:37:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:32:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

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 19:48:35
DataPoint Verified.		09 Nov 2020 18:14:00
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User closed query 'PV Query: Please advise why subject remained hospitalized until 17 Sep but event ended on 14 Sep. ' (Site from Safety).		29 Jan 2021 17:40:30
Query 'PV Query: Please advise why subject remained hospitalized until 17 Sep but event ended on 14 Sep. ' answered with 'updated' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	28 Jan 2021 15:57:25
User opened query 'PV Query: Please advise why subject remained hospitalized until 17 Sep but event ended on 14 Sep. ' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 22:01:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
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). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:18:32
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). Please leave query open until information is received.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:15:11
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). Please leave query open until information is received.' (Site from Safety).		25 Nov 2020 17:15:05

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED SITE TO REPORT BEING ADMITTED TO HOSPITAL FOR THE SAE. SUBJECT IS STILL THERE AND PLANS ON BEING RELEASE IN THE MORNING ON 15 SEP 2020. SITE IS SENDING A FORM FOR MEDICAL RELEASE.- UPDATE- SUBJECT WENT TO ER AND GOT ADMITTED ON 12/SEP/2020. FOR A GASTROINTESTINAL BLEED. SUBJECT WAS DISMISSED TO HOME ON 17/SEP/2020.' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:58:19
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). Please leave query open until information is received.' answered with 'updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:47
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:12
User entered 'SUBJECT CALLED SITE TO REPORT BEING ADMITTED TO HOSPITAL FOR THE SAE. SUBJECT IS STILL THERE AND PLANS ON BEING RELEASE IN THE MORNING ON 15 SEP 2020. SITE IS SENDING A FORM FOR MEDICAL RELEASE.- UPDATE- SUBJECT WENT TO ER AND GOT ADMITTED ON 13/SEP/2020. FOR A GASTROINTESTINAL BLEED. SUBJECT WAS DISMISSED TO HOME ON 17/SEP/2020.' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:55:12
User closed query 'PV Query: Please provide unabbreviated lab test name for BCR.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:31:43
Query 'PV Query: Please provide unabbreviated lab test name for BCR.' answered with ' Breakpoint cluster region' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:30:29
User opened query 'PV Query: Please provide unabbreviated lab test name for BCR.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:14:44

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
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). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:13:56
DataPoint Verified.		09 Nov 2020 18:14:00
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). Please leave query open until information is received. ' (Site from Safety).		06 Nov 2020 15:16:09
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' (Site from Safety).		06 Nov 2020 15:16:04
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). Please leave query open until information is received. ' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 15:01:57

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' answered with '09/13/2020 Labs- WBC-18.5, HGB,6.2,HCT-18.3, PLT-169, K-4.6, CL-107, CO2-22, BUN-79, CREA-1.98, Calcium- 8.4, PROT-5.7, ALKPHOS- 39, ALT-11, AST-9, Glucose- 277. 09/14/2020: K-4.9, CL-114, Aniongap- 3, CO2-25, BUN-82, CREA-1.70, BCR-48, Glucose-136, Calcium-8.4, Prot-4.7, Albumin- 3.0, AST-15, ALT-8, ALKPHOS-31, BILT-0.8, GFR-38, WBC-12.8, RBC- 2.26, HGB-7.2, HCT-21.4, MCV-94.8, MCHC-33.6, RDW-14.6, PLT- 126, EOSPCT-0.5, ANEUT-9.8. 09/15/2020- WBC-10.8, RBC-2.72, HGB-8.7, HCT24.6. 09/16/2020- WBC-9.3, RBC-3.25, HGB-10.2, HCT-29.4, 09/17/2020- BUN-41, CREA-1.56, WBC-8.7, RBC-3.25, HGB-10.4,. Subject has also received 6 units of blood during this time. ' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 15:01:43
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:06:53
User entered 'SUBJECT CALLED SIT TO REPORT BEING ADMITTED TO HOSPITAL FOR THE SAE. SUBJECT IS STILL THERE AND PLANS ON BEING RELEASE IN THE MORNING ON 15 SEP 2020. SITE IS SENDING A FORM FOR MEDICAL RELEASE.- UPDATE- Subject went to ER and got admitted on 13/Sep/2020. for a gastrointestinal bleed. Subject was dismissed to home on 17/sep/2020.' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	05 Nov 2020 14:06:53
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). Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 11:52:52

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
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. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 11:51:31
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is received.' (Site from Safety).		22 Oct 2020 23:39:09
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). Please leave query open until information is received.' (Site from Safety).		22 Oct 2020 23:38:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).		22 Oct 2020 23:38:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is received.' answered with 'there was no COVID testing done during hospital stay ' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	21 Oct 2020 12:22:27
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). Please leave query open until information is received.' answered with 'AWAITING MED RECORDS' (Site from Safety).	Russell Herstein (b) (4) (b) (4)	21 Oct 2020 02:22:11

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' answered with 'AWAITING MED RECORDS' (Site from Safety).	Russell Herstein (b) (4) (b) (4)	21 Oct 2020 02:22:07
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:40:55
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). Please leave query open until information is received.' (Site from Safety).		19 Oct 2020 16:40:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).		19 Oct 2020 16:40:28
Query '*REQUERY* PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' canceled (Site from Safety).		19 Oct 2020 16:38:45
User opened query '*REQUERY* PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until informatio is received.' (Site from Safety).		19 Oct 2020 16:38:38
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is received.' (Site from Safety).		12 Oct 2020 13:56:18

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Narrative

Audit	User	Time (GMT)
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). Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:56:17
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' (Site from Safety).		12 Oct 2020 13:56:15
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is received.' answered with 'waiting for medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:12:34
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). Please leave query open until information is received.' answered with 'waiting on medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:12:26
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' answered with 'waiting for medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 19:12:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:11:00

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Narrative

Audit	User	Time (GMT)
	(b) (4), (b) (6)	
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). Please leave query open until information is received.' (Site from Safety).		08 Oct 2020 18:10:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received ' (Site from Safety).		08 Oct 2020 18:10:37
User closed query 'PV Query: Please provide subject's signs and symptoms.' (Site from Safety).		02 Oct 2020 12:08:56
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		02 Oct 2020 12:08:54
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).' (Site from Safety).		02 Oct 2020 12:08:53
User closed query 'PV Query: Please clarify if concomitant medication reported as "capatin allergy" should be Capoten allergy. Please updated if applicable.' (Site from Safety).		02 Oct 2020 12:08:51
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Sit from Safety).		02 Oct 2020 12:08:49
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		02 Oct 2020 12:08:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32

US3032277
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:17
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please clarify if concomitant medication reported as "capatin allergy" should be Capoten allergy. Please updated if applicable.' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:14:38
Query 'PV Query: Please provide subject's signs and symptoms.' answered with 'abd pain' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:14:27
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'waiting on medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:14:20
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).' answered with 'waiting on medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:14:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'waiting on medical records' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:13:53
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'there were none' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 18:13:31
User opened query 'PV Query: Please provide subject's signs and symptoms.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 14:38:54
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		24 Sep 2020 14:38:30
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).' (Site from Safety).		24 Sep 2020 14:38:12

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify if concomitant medication reported as "capatin allergy" should be Capoten allergy. Please updated if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 14:37:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		24 Sep 2020 14:36:56
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		24 Sep 2020 14:36:43
User entered 'Subject called sit to report being admitted to hospital for the SAE. Subject is still there and plans on being release in the morning on 15 Sep 2020. site is sending a form for medical release.'	Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	14 Sep 2020 20:31:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	14 Sep 2020 20:31:03

US3032277

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:54:17

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '0'	System	14 Sep 2020 20:31:03

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:40:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
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 Aug 2020 00:42:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:42:29
Data point term sent to Coder	System	21 Aug 2020 00:41:50
User entered 'aspirin'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:48:35
DataPoint Verified.		3 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:08:34
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'DATA ENTERED' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:23:20
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:05:49
User entered 'blood clots'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '325'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:48:35
DataPoint Verified.		3 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:41:18
User entered 'un UNK 2013'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:41:18

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:46:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:46:35
Data point term sent to Coder	System	11 Nov 2020 17:45:35
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:44:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4) (b) (4)	01 Oct 2020 22:05:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:43:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:43:29
Data point term sent to Coder	System	21 Aug 2020 00:42:53
User entered 'allopurinol'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User closed query 'Per DM CLR: Prophylaxis = YES, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:08:51
Query 'Per DM CLR: Prophylaxis = YES, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify.' answered with 'DATA CORRECTED' (Site from DM).		14 Sep 2020 23:25:29
User entered 'No (N)' reason for change: Data Entry Error		14 Sep 2020 23:25:23
User opened query 'Per DM CLR: Prophylaxis = YES, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		10 Sep 2020 10:15:56
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:36:24
Query 'Per DM CLR: Please specify the location of GOUT. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' answered with 'Data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:45:04
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:44:57
User entered 'GOUT bilateral feet' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:44:57
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:29:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Query 'Per DM CLR: Please review Indication and please update to specify the location of manifestation of Gout. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:57:54
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of manifestation of Gout. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:57:35
User entered 'gout'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '150'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:42:01
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:42:01

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:42:01

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:47:36
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 Nov 2020 17:47:36
Data point term sent to Coder	System	11 Nov 2020 17:46:40
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:43:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:43:29
Data point term sent to Coder	System	21 Aug 2020 00:42:51
User entered 'amlodipine'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:25
User entered 'HYPERTENSION' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'medical history: hypertension'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '2.5'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

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US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:42:44
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

FDA-CBER-2022-1614-0166607

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:42:44

FDA-CBER-2022-1614-0166610

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '2'	System	21 Aug 2020 00:42:44

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:42:44

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:02:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:02:35
Data point term sent to Coder	System	11 Nov 2020 17:46:40
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 08:23:12
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 Aug 2020 08:23:12
Data point term sent to Coder	System	21 Aug 2020 00:43:54
User entered 'pravastatin'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 17:46:37
User entered 'HYPERCHOLESTEROLEMIA' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 17:46:37
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	01 Oct 2020 22:05:32
User entered 'medical history: hypercholesterolemia'	(b) (4) Kelsey Kelley (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '20'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

FDA-CBER-2022-1614-0166622

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:43:27
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:43:27

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:43:27

FDA-CBER-2022-1614-0166630

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:43:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
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)	24 Nov 2020 23:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:32:57
Data point term sent to Coder	System	24 Nov 2020 23:32:15
Coding entries removed.	Linden DeBoer (b) (4)	24 Nov 2020 23:31:22
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)	19 Nov 2020 11:36:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:36:59
Data point term sent to Coder	System	11 Nov 2020 17:47:41
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
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 Aug 2020 04:56:16

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US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
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 Aug 2020 04:56:16
Data point term sent to Coder	System	21 Aug 2020 00:43:54
User entered 'losartan'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:45
User entered 'HYPERTENSION' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'medical history: hypertension'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '50'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

FDA-CBER-2022-1614-0166640

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:31:22
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:31:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Intraocular (INTRAOCULAR)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:43:53
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:43:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '2'	System	21 Aug 2020 00:43:53

FDA-CBER-2022-1614-0166648

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:43:53

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:48:34
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 Nov 2020 17:48:34
Data point term sent to Coder	System	11 Nov 2020 17:47:43
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 05:14:18
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 Aug 2020 05:14:18
Data point term sent to Coder	System	21 Aug 2020 00:44:54
User entered 'glimepiride'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:53
User entered 'DIABETES MELLITUS TYPE 2' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:46:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'medical history: diabetes mellitus type 2'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '3'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:44:27
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:44:27

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User		Time (GMT)
Data hard locked.	(b) (4), (b) (6)		26 Apr 2021 19:48:35
DataPoint Verified.			13 Apr 2021 16:05:40
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	12 Nov 2020 22:23:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	12 Nov 2020 22:23:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	12 Nov 2020 22:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	12 Nov 2020 22:08:35
Data point term sent to Coder	System		11 Nov 2020 17:47:41
Coding entries removed.	Kelsey Kelley (b) (4)	(b) (4)	11 Nov 2020 17:47:01
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4)	01 Oct 2020 22:05:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	21 Aug 2020 06:29:13
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 Aug 2020 06:29:13
Data point term sent to Coder	System		21 Aug 2020 00:45:55
User entered 'finastride'	Kelsey Kelley (b) (4)	(b) (4)	21 Aug 2020 00:45:00

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US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:47:01
User entered 'ENLARGED PROSTATE' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:47:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'medical history: enlarged prostate'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '5'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

FDA-CBER-2022-1614-0166673

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:45:00
User entered 'un UNK 2005'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4)	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:00

FDA-CBER-2022-1614-0166683

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:45:00

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:45:00

FDA-CBER-2022-1614-0166686

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:48:34
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 Nov 2020 17:48:34
Data point term sent to Coder	System	11 Nov 2020 17:47:44
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:47:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4) (b) (4)	01 Oct 2020 22:05:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:46:56
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 Aug 2020 00:46:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:46:21
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 Aug 2020 00:46:21
Data point term sent to Coder	System	21 Aug 2020 00:45:55
User entered 'carvedilol'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:17
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:47:08
User entered 'HYPERTENSION' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 17:47:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'medical history: hypertension'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '6.25'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:45:40
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 22:05:32
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '2'	System	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	21 Aug 2020 00:45:40

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
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: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:34:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:34:00
Data point term sent to Coder	System	24 Nov 2020 23:33:16
User entered 'Vitamin B12'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Dec 2020 16:21:31
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:10:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Data corrected' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 22:56:10
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 22:52:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 22:52:48
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:58:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Nutritional Supplement'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '250'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'ug (ug)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

FDA-CBER-2022-1614-0166710

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'twice daily (BID)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Oral (ORAL)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'UN UNK 1998'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '0'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:32:55

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '2'	System	24 Nov 2020 23:32:55

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	24 Nov 2020 23:32:55

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 23:49:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 23:49:59
Data point term sent to Coder	System	24 Nov 2020 23:35:16
User entered 'Atrovent'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User closed query 'Per DM CLR: Please note that thi condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).		10 Dec 2020 06:11:39
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'Is recorded on MH line 12 ' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 22:52:26
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:59:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Seasonal Allergies'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '2'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

FDA-CBER-2022-1614-0166726

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Other (OTHER)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

FDA-CBER-2022-1614-0166727

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Puffs'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'as needed (PRN)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'UN UNK 2000'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '0'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 23:34:47

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	24 Nov 2020 23:34:47

FDA-CBER-2022-1614-0166738

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	24 Nov 2020 23:34:47

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:31:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:31:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
Data point term sent to Coder	System	18 Jan 2021 15:49:15
User entered 'packed red blood cells'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'Acute duodenal ulcer with hemorrhage'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '1'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'unit'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

FDA-CBER-2022-1614-0166746

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '13 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:31:05
	(b) (4)	
User entered '15 Sep 2020'	Kelsey Kelley (b) (4)	18 Jan 2021 15:49:11
	(b) (4)	

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered empty.	System	18 Jan 2021 15:49:11

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:31:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:31:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
Data point term sent to Coder	System	18 Jan 2021 15:50:15
User entered 'pantoprazole'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'acute duodenal ulcer with hemorrhage'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '40'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

FDA-CBER-2022-1614-0166762

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '13 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '16 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '2'	System	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	18 Jan 2021 15:50:05

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	18 Jan 2021 15:50:05

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:32:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:32:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
Data point term sent to Coder	System	18 Jan 2021 15:51:16
User entered 'pantoprazole'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'acute duodenal ulcer with hemorrhage'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '40'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).		17 Feb 2021 02:04:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:57:07
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:13
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:06
User entered '12 Sep 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:06
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:00:38
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '17 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:57:07
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:06
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:06
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:57:07
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:06
User entered '17 Sep 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 22:12:06
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Jan 2021 19:31:05
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	18 Jan 2021 15:50:54

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '2'	System	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '1'	System	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:17

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User entered '804 (804)'	System	18 Jan 2021 15:50:54

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:54:17

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:05
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:56:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 14:56:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	21 Aug 2020 00:40:14

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '14 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:05:29
User entered '13 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:01:49

FDA-CBER-2022-1614-0166796

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:54:17

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Esophagastroduodenalscopy'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:01:49

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Adverse Event (AE)'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:01:49

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:54:17

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:01:49

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:54:17

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '14 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:05:23
User entered '13 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:12

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:54:17

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Colonoscopy'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:12

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Adverse Event (AE)'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:12

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:54:17

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:12

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:54:17

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered '14 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:05:13
User entered '12 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:31

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:54:17

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Transfusion of Packed Red Blood Cells'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:31

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:54:17

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered 'Adverse Event (AE)'	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:31

US3032277

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:54:17

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:05:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
User entered empty.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:02:31

US3032277

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:54:17

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Nov 2020 21:42:39
User closed query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Nov 2020 23:02:04
User entered '1 Oct 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Nov 2020 23:02:04
User opened query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Nov 2020 23:01:57
User entered '1 Nov 2020'	Linden DeBoer (b) (4) (b) (4)	09 Nov 2020 23:01:57

US3032277

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:54:17

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:37
User closed query 'Per CDM: Please note that there is a SAE recorded with Action taken = Investigational product withdrawn (#1). Please review the primary reason for discontinuation should be updated to SAE. If yes, please update as appropriate and record SAE record number in the Other, specify field on this page, else clarify. ' (Site from DM).		22 Nov 2020 22:28:05
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Query 'Per CDM: Please note that there is a SAE recorded with Action taken = Investigational product withdrawn (#1). Please review the primary reason for discontinuation should be updated to SAE. If yes, please update as appropriate and record SAE record number in the Other, specify field on this page, else clarify. ' answered with 'data updated ' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:32:05
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:31:55
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:31:55
User opened query 'Per CDM: Please note that there is a SAE recorded with Action taken = Investigational product withdrawn (#1). Please review the primary reason for discontinuation should be updated to SAE. If yes, please update as appropriate and record SAE record number in the Other, specify field on this page, else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:46:04
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Nov 2020 21:42:39
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Linden DeBoer (b) (4) (b) (4)	09 Nov 2020 23:01:57

US3032277

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:54:17

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 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:37
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:28:20
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 01:57:10
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'data updated ' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	16 Mar 2021 13:47:17
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	16 Mar 2021 13:47:08
User entered '#1 for row 1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	16 Mar 2021 13:47:08
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then SAE specify field must include '#' symbol and 'AE logline number'. Please consider updating SAE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:58:11
Query 'Per CDM: Per sponsor review, please update specify field to include both SAE and number. (i.e. SAE #1).' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:57:48
User opened query 'Per CDM: Per sponsor review, please update specify field to include both SAE and number. (i.e. SAE #1).' (Site from DM).		02 Mar 2021 19:11:50

US3032277

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note that Reason for dosing discontinuation is SAE #1; however on the AE page Action taken with investigational product = Not applicable. Please review if this should be changed to Investigational product withdrawn and update the AE page as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 04:20:37
Query 'Per CDM: Please note that Reason for dosing discontinuation is SAE #1; however on the AE page Action taken with investigational product = Not applicable. Please review if this should be changed to Investigational product withdrawn and update the AE page as appropriate, else clarify. ' answered with 'updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 15:15:36
User opened query 'Per CDM: Please note that Reason for dosing discontinuation is SAE #1; however on the AE page Action taken with investigational product = Not applicable. Please review if this should be changed to Investigational product withdrawn and update the AE page as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:08:28
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:31:55
User entered 'sae line 1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:31:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Nov 2020 21:42:39
User entered 'withdrawal of consent by patient due to unforeseen health issues'	Linden DeBoer (b) (4) (b) (4)	09 Nov 2020 23:01:57

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:17

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered '1 Oct 2020'	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:17

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User closed query 'Per CDM: Per End of Study form subject Withdrew consent due to unforeseen health issues. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn (#1). Please review if this relates to this event and the primary reason for discontinuation should be updated to SAE. If yes, please update as appropriate and record SAE record number in the Other, specify field on this page, else clarify. ' (Site from DM).		22 Nov 2020 22:28:15
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Query 'Per CDM: Per End of Study form subject Withdrew consent due to unforeseen health issues. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn (#1). Please review if this relates to this event and the primary reason for discontinuation should be updated to SAE. If yes, please update as appropriate and record SAE record number in the Other, specify field on this page, else clarify. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:32:49
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:32:32
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:32:32
User opened query 'Per CDM: Per End of Study form subject Withdrew consent due to unforeseen health issues. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn (#1). Please review if this relates to this event and the primary reason for discontinuation should be updated to SAE. If yes, please update as appropriate and record SAE record number in the Other, specify field on this page, else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:55:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

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 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:36
User closed query 'Per CDM, re-query: Please note that only the SAE log line number is to be recorded in this field (i.e. SAE #1, etc.). Kindly update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:40:05
Query 'Per CDM, re-query: Please note that only the SAE log line number is to be recorded in this field (i.e. SAE #1, etc.). Kindly update as appropriate.' answered with 'CHANGED DATA PER QUERY' (Site from DM).	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 14:31:02
User entered 'SAE #1' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 14:30:54
Query 'Per CDM, re-query: Please note that only the SAE record line number should be recorded in this field. Kindly update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:48:53
User opened query 'Per CDM, re-query: Please note that only the SAE log line number is to be recorded in this field (i.e. SAE #1, etc.). Kindly update as appropriate.' (Site from DM).		24 Nov 2020 10:48:47
User opened query 'Per CDM, re-query: Please note that only the SAE record line number should be recorded in this field. Kindly update as appropriate. ' (Site from DM).		24 Nov 2020 10:44:54
User closed query 'Per CDM; please consider simply recording the record line number per CCGs and remove all other details.' (Site from DM).		24 Nov 2020 06:03:29
Query 'Per CDM; please consider simply recording the record line number per CCGs and remove all other details.' answered with 'CHANGED DATA PER QUERY' (Site from DM).	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 21:01:39
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 21:01:27
User entered 'SEE LOG LINE 1' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 21:01:27

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:17

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

Audit	User	Time (GMT)
User opened query 'Per CDM; please consider simply recording the record line number per CCGs and remove all other details.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:27:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:32:43
User entered 'SUBJECT DECIDED IT WAS IN THE BEST INTEREST TO WITHDRAWAL CONSENT FROM THE STUDY TO UNFORESEEN HEALTH ISSUES NOT VACCINE RELATED.- SEA Log Line 1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 18:32:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 16:21:53
User entered 'subject decided it was in the best interest to withdrawal consent from the study to unforeseen health issues not vaccine related.' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:21:53
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 16:20:24
User entered empty.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:17

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered empty.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered empty.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:17

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered empty.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

US3032277

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:17

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		13 Apr 2021 16:04:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered empty.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 16:20:24

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166823

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:54:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '15/Sep/2020 11:45'	System	15 Sep 2020 15:45:25

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 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 14:54:17
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
User entered '02/Oct/2020 08:09'	System	02 Oct 2020 12:09:20

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		12 Oct 2020 13:56:34
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:21:20
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:09:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:04:43
User entered '12/Oct/2020 09:56'	System	12 Oct 2020 13:56:44

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		22 Oct 2020 22:48:11
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 14:04:43
User entered '1'	(b) (4) / (b) (4), (b) (6)	12 Oct 2020 13:56:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 14:54:17
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 16:42:22
User entered '22/Oct/2020 22:48'	System	22 Oct 2020 22:48:23

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 14:54:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 15:16:38
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 22:48:23

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166911

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:54:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
User entered '06/Nov/2020 15:16'	System	06 Nov 2020 15:16:53

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:51:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:48:17
User entered '1'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:16:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166927

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166928

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

FDA-CBER-2022-1614-0166939

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:54:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
User entered '13/Nov/2020 17:51'	System	13 Nov 2020 17:51:36

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:32:06
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:52:51
User entered '1'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166946

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166947

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166948

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166949

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166953

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:54:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
User entered '20/Nov/2020 10:32'	System	20 Nov 2020 15:32:23

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 15:18:45
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:30:20
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:32:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0166963

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:54:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:36
User entered '30/Nov/2020 10:18'	System	30 Nov 2020 15:18:57

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:39:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:36
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:18:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form (9)
Generated On: 09 Jun 2021 14:54:17
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '19/Jan/2021 10:39'	System	19 Jan 2021 15:39:19

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:53:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:39:22
User entered '1'		19 Jan 2021 15:39:19

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'USA-US032-2020-MRNA-1273-P301000003'	System	15 Sep 2020 15:44:51

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:17
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

FDA-CBER-2022-1614-0167000

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Yes (Y)'	System	15 Sep 2020 15:44:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:54:17

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'No (N)'	System	15 Sep 2020 15:44:51

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Keith'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:59:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 15:45:15
User entered 'Vrbicky'	System	15 Sep 2020 15:44:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

FDA-CBER-2022-1614-0167009

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
DataPoint Verified.		09 Nov 2020 18:13:40
Reviewed for Safety.		02 Oct 2020 12:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:52:24
User entered 'US' (non-conformant).	System	15 Sep 2020 15:45:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:53:32
User entered '10'	System	29 Jan 2021 17:28:39
Signature has been broken.	System	19 Jan 2021 15:39:19
User entered '9'	System	19 Jan 2021 15:39:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:36
Signature has been broken.	System	30 Nov 2020 15:18:57
User entered '8'	System	30 Nov 2020 15:18:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:30:20
Signature has been broken.	System	20 Nov 2020 15:32:23
User entered '7'	System	20 Nov 2020 15:32:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:52:51
Signature has been broken.	System	13 Nov 2020 17:51:36
User entered '6'	System	13 Nov 2020 17:51:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	06 Nov 2020 17:48:17
Signature has been broken.	System	06 Nov 2020 15:16:53
User entered '5'	System	06 Nov 2020 15:16:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Oct 2020 16:42:22
Signature has been broken.	System	22 Oct 2020 22:48:23
User entered '4'	System	22 Oct 2020 22:48:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 14:04:43
Signature has been broken.	System	12 Oct 2020 13:56:44
User entered '3'	System	12 Oct 2020 13:56:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:21:20
Signature has been broken.	System	02 Oct 2020 12:09:20
User entered '2'	System	02 Oct 2020 12:09:20
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:59:25
User entered '1'	System	15 Sep 2020 15:45:25

US3032277
Folder: SAE USA-US032-2020-MRNA-1273-P301000003
Form: Safety Report Form (10)
Generated On: 09 Jun 2021 14:54:17
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:53:32
User entered '29/Jan/2021 12:28'	(b) (4) System	29 Jan 2021 17:28:39

US3032277

Folder: SAE USA-US032-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:54:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:53:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:29:03
User entered '1'		29 Jan 2021 17:28:39