US3432295 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:37:11

All time stamps listed in this document are displayed in GMT

Participant ID   US3432295

mRNA-1273-P301 Completion Guidelines

US3432295

Folder: Screening

Form: Visit Date

Data signed: (b) (4)   **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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Date of Birth (MMM yyyy)	(b) (6) 1936
Age	83
Age Units	YEARS
Age (Derived)	83
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

US3432295

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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Date of Informed Consent *(dd MMM yyyy)*	26 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

US3432295

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: ⬛ (b) (4) ⬛ **19 Feb 2021 02:21:11**

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Did the participant meet all eligibility criteria?   Yes ⬤

No ◯

Were any significant conditions reported?   Yes ●

No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: ▓▓▓▓ (b) (4) ▓▓▓▓ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	CHRONIC LYMPHOCYTIC LEUKEMIA (NO THERAPY, MONITORED)
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)	

US3432295

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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Condition	HYPOTHYROIDISM
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)	

US3432295

Folder: Screening

Form: Medical History (3)

Data signed: ▨▨▨ (b) (4) ▨▨▨ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4)   **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	IDIOPATHIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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Condition	BRADYCARDIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3432295

Folder: Screening

Form: Medical History (8)

Data signed: ░░░░░░ (b) (4) ░░░░░░ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	FUCH'S DYSTROPHY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: ░░░░░ (b) (4) ░░░░░ **19 Feb 2021 02:21:11**

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Condition	RENAL CYST
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: ▨▨▨ (b) (4) ▨▨▨ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	CKD STAGE 3
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	OSA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: ▓▓▓▓▓ (b) (4) ▓▓▓▓▓ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	OPEN ANGLE GLAUCOMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	AORTIC ROOT DILATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (14)

Data signed: ███████ (b) (4) ███████ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	NIGHT SWEATS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: ███████ (b) (4) ███████ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	RIGHT AXILLARY LYMPTHODENOPATHY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Condition	SOFT TISSUE THICKENING IN L TONSILLAR FOSSA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3432295

Folder: Screening

Form: Vital Signs

Data signed: ████ (b) (4) ████ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	10:11 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:11
Height *(xxx.x)*	171 cm
Weight *(xxx.x)*	68.4 kg
BMI *(xxx.x)*	23.39181 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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Was the physical examination performed?   Yes ●

                                                       No ○

Date of examination *(dd MMM yyyy)*   26 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:21:11

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Occupational Risk

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

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 02:21:11**

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Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 02:21:11

Generated On: 09 Jun 2021 17:37:11

What was the date of randomization? *(dd MMM yyyy)*	26 AUG 2020
What was the participant's randomization number?	188217

In what Cohort was the participant enrolled?

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

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

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

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)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	10:11 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:11
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	046 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	057 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

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)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	11:42 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:42
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	044 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	058 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Was the physical examination performed?   Yes ◯

                                                                                                    No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

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)*	26 AUG 2020
What was the treatment time? *(00:00-23:59)*	11:12 (24 HR)
Treatment Date and Time (derived)	26 AUG 2020 11:12
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

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	26 AUG 2020
Collection time *(00:00-23:59)*	10:25 (24 HR)
Collection date and time (derived)	26 AUG 2020 10:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Collection date *(dd MMM yyyy)*   26 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	26 AUG 2020 10:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

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**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	26 AUG 2020 11:47
PC Open Date & Time	26 AUG 2020 11:32
PC Close Date & Time	26 AUG 2020 14:02

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TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	26 AUG 2020 22:23
PC Open Date & Time	26 AUG 2020 14:57
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-2604470

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:37:11

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	28 AUG 2020 00:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:37:11

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**	97.4 °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	28 AUG 2020 22:31
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:37:11

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	29 AUG 2020 22:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.6 °F

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

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

PC Time Stamp	30 AUG 2020 22:34
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	31 AUG 2020 22:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:11

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**	99.1 °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	01 SEP 2020 22:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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	26 AUG 2020 11:47
PC Open Date & Time	26 AUG 2020 11:32
PC Close Date & Time	26 AUG 2020 14:02

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	26 AUG 2020 22:24
PC Open Date & Time	26 AUG 2020 14:57
PC Close Date & Time	27 AUG 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

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	28 AUG 2020 00:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 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	28 AUG 2020 22:31
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 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	29 AUG 2020 22:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

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	30 AUG 2020 22:35
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT	DAY 6

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

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

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

PC Time Stamp	31 AUG 2020 22:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

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	01 SEP 2020 22:10
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:37:11

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 ◯

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

PC Time stamp	26 AUG 2020 11:49
PC Open Date & Time	26 AUG 2020 11:32
PC Close Date & Time	26 AUG 2020 14:02

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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 ○

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

No ●

Yes ○

PC Time stamp	26 AUG 2020 22:25
PC Open Date & Time	26 AUG 2020 14:57
PC Close Date & Time	27 AUG 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:37:11

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	28 AUG 2020 00:04
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:11

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	28 AUG 2020 22:32
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

TIMEPOINT	DAY 4

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ○
- No interference with activity ●
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

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

	Yes ◯
PC Time stamp	29 AUG 2020 22:07
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:37:11

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	30 AUG 2020 22:36
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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

	Yes ◯
PC Time stamp	31 AUG 2020 22:41
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11

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	01 SEP 2020 22:11
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

TIMEPOINT	DAY 8

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯

PC Time stamp	02 SEP 2020 21:59
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3432295
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:37:11

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	02 SEP 2020 22:00
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3432295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 02 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3432295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3432295

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: ▨▨▨ (b) (4) ▨▨▨ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3432295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **04 Apr 2021 20:47:43**

Generated On: 09 Jun 2021 17:37:11

| Was Contact Attempted? | Yes ⬤ |
| | No ⬭ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 16 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ⬭ |

Comments

If Contact Not Made, please provide Comments _____

US3432295

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: ▨▨▨ (b) (4) ▨▨▨ **19 Feb 2021 02:21:11**

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3432295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **04 Apr 2021 20:47:43**

Generated On: 09 Jun 2021 17:37:11

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   VISIT2

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 20:47:43

Generated On: 09 Jun 2021 17:37:11

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

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

FDA-CBER-2022-1614-2604511

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **04 Apr 2021 20:47:43**

Generated On: 09 Jun 2021 17:37:11

Was the physical examination performed?　　　　　　　　　　　　　　Yes ◯

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ⬤

Date of examination *(dd MMM yyyy)*　　　　　　　　　　＿＿＿＿＿＿＿＿

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

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: ▓▓▓▓ (b) (4) ▓▓▓▓ 04 Apr 2021 20:47:43

Generated On: 09 Jun 2021 17:37:11

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? _____

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

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

Treatment Date and Time (derived) _____

Which arm was used to give treatment?	Left Arm ⭕
	Right Arm ⭕

What was the frequency of the study treatment dosing? _____

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

Was the sample collected?   Yes ◯

                                                             No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

FDA-CBER-2022-1614-2604514

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4)   **04 Apr 2021 20:47:43**

Generated On: 09 Jun 2021 17:37:11

Collection date *(dd MMM yyyy)*

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

US3432295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: ████(b) (4)████ **04 Apr 2021 20:47:43**

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?   Yes ◯

                                                                    No ⬤

Continuing Flag

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:37:11

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

US3432295
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:37:11

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact

Clinic Visit - Scheduled ◯
Clinical Visit - Unscheduled ◯
Safety Call ◯
Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?

Yes ◯
No ◯

US3432295
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 17:37:11

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3432295

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

Form: Visit Date

Data signed: (b) (4)   **03 May 2021 15:24:40**

Generated On: 09 Jun 2021 17:37:11

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 _____

US3432295

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

Form: Unblinding

Data signed: [(b) (4)] **28 Apr 2021 21:59:25**

Generated On: 09 Jun 2021 17:37:11

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

US3432295

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **03 May 2021 15:24:40**

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?   Yes ◯

                                                                     No ◯

Collection date *(dd MMM yyyy)*   _____

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

Collection date and time (derived)   _____

US3432295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **03 May 2021 15:24:40**

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?   Yes ◯

                                                                          No ◯

Collection date *(dd MMM yyyy)*

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

Collection Date and Time (derived)

US3432295

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Did the participant experience any adverse events? Yes ●

No ○

If Yes, enter details on the Adverse Events form.

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4)   **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

AEID	USA-US078-2020-MRNA-1273-P30 1000002
Adverse event	DIFFUSE BULLOUS RASH (NON-URTICARIAL)

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)*	
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)*	17 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	24 SEP 2020

Admitted to ICU?   Yes ○   No ●   Unknown ○

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4)   25 Apr 2021 11:12:09

Generated On: 09 Jun 2021 17:37:11

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	False

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

17SEP2020: PPT DEVELOPED BLISTERS ON HIS FEET ON 12SEP2020 THAT SPREAD UP HIS LEGS OVER THE FOLLOWING DAYS. HE HAD A VIRTUAL VISIT WITH HIS PCP AND THEN A DERMATOLOGIST ON 15SEP2020, TODAY THE BLISTERS HAVE SPREAD TO INVOLVE MORE OF HIS BODY. HE SPOKE TO HIS PCP AND WILL SEEK ADDITIONAL EVALUATION. 21SEP2020 UPDATE: PARTICIPANT WAS ADMITTED TO BIDMC HOSPITAL ON 17SEP2020 AFTER WE LAST SPOKE. HE REMAINS HOSPITALIZED DUE TO GENERALIZED BLISTERING RASH. COVID-19 PCR NEGATIVE AT HOSPITAL. NO SPECIFIC DIAGNOSIS FOR RASH. POSSIBLE HYPERSENSITIVITY REACTION. NO OTHER SYMPTOMS. NOW IMPROVING. ANTICIPATED DISCHARGE TO HOME SOON. 02OCT20: NO ILLICIT DRUGS, OTC OR HERBAL MEDICATIONS. DRINKS 7-8 DRINKS/WEEK. ADDITIONAL SYMPTOMS: WORSENING NIGHT SWEATS AND FATIGUE. TREATMENTS PRESCRIBED 15SEP2020-

TRIAMCINOLONE ACETONIDE CREAM AND CICLOPIROX CREAM. NEW MEDICATION IN HOSPITAL- TP CLOBETASOL PROPIONATE 0.05% 1 APPLICATION. NEW DISCHARGE MEDICATION- ALLOPURINOL 200 MG PO DAILY. NOTABLE LAB RESULTS: 17SEP2020 WBC 25.7, ATYPICAL 1%, PLT 176, BUN 53, CREATINE 2.2, POTASSIUM 5.4, LDH 381 24SEP2020 WBC 27.7, HGB 10.0, HCT 31.4, GLUCOSE, 125, UREAN 35, PLT CT 155, CL 109, HCO3 21, ALBUMIN 3, CALCIUM 8.2, URIC ACID 7.6 AXILLARY BIOPSY- B CELL LYMPHOPROLIFERATIVE DISORDER, ULTRASOUND NECK- SOFT TISSUE THICKENING IN LEFT TONSILLAR FOSSA, MRI NECK- CONGLOMERATE R AXILLARY & SUPRACLAVICULAR LYMPHADENOPATHY, NOTE FROM SKIN EXAM: DIFFUSE PAUPULAR/VESICULAR/BULLA E RASH WITH OPEN BLISTERS AND YELLOWISH SEROUS DRAINAGE

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

FDA-CBER-2022-1614-2604528

US3432295

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: ████████ (b) (4) ████████ **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

AEID	USA-US078-2020-MRNA-1273-P30 1000002
Adverse event	SEVERE SYSTEMIC INFLAMMATORY SYNDROME IN THE SETTING OF CLL

Was this a medically-attended AE?　　Yes ●　No ○

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ○　No ●

Start date *(dd MMM yyyy)*　　01 OCT 2020

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

AE start date and time (derived)

Ongoing?　　Yes ○　No ●

　If not Ongoing, end date *(dd MMM yyyy)*　　02 OCT 2020

　End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity　　Grade 1/Mild ○　Grade 2/Moderate ○　Grade 3/Severe ○　Grade 4 ●

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)

Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	01 OCT 2020
Hospital Discharge Date *(dd MMM yyyy)*	02 OCT 2020
Admitted to ICU?	Yes ●　No ○

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

	Unknown ◯
Number of Days in ICU	2
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	True
Concomitant Medication	False
Concomitant Procedure	False
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

02OCT20:PT HAD BEEN DOING WELL AT HOME SINCE DISCHARGE FROM HOSPITAL 24SEP2020 FOR DIFFUSE BULLOUS RASH. ON 01OCT2020, HE REPORTEDLY DEVELOPED WORSENING OF RASH, FEVER, AND DIARRHEA, PRESENTED TO BIDMC HOSPITAL AND WAS ADMITTED. DOING POORLY THERE, SUFFERED CARDIAC ARREST. RECOVERED WITH RESUSCITATION, REMAINS IN ICU THERE. SPOKE WITH ICU MEDICAL TEAM AND PATIENTS WIFE FOR THIS INFORMATION, ALSO SUBMITTING MEDICAL RECORDS. ONCOLOGY TEAM THERE EVALUATING TO DETERMINE WHETHER CURRENT EVENT MAY BE DUE TO TRANSFORMATION OF HIS UNDERLYING CLL. 03OCT2020: UPDATE FROM DEATH NOTE- PARTICIPANT ADMITTED WITH ACUTE SOB HAD RECENT HOSPITALIZATION FOR RASH. FOUND TO HAVE ACUTE RESPIRATORY FAILURE. PEA ARREST 02OCT2020. PURPURA FULMINANS, COVERED ALMOST ALL BODY. PARTICIPANT DESIGNATED CMO. TIME OF DEATH 16:45 ON 02OCT2020.

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)	1

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: [(b) (4)] **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

AEID	
Adverse event	SUPRACLAVICULAR LYMPHADENOPATHY
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)*	22 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)*	02 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

Number of Days in ICU	
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	True
Concomitant Medication	False
Concomitant Procedure	False

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

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **19 Feb 2021 02:21:10**

Generated On: 09 Jun 2021 17:37:11

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)] **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	LEVOTHYROXINE

Prophylaxis

Yes ⭕

No ⬤

Indication	HYPOTHYROIDISM
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 ⭕

PRODUCTION RELEASE (v12.003 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 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 (2)

Data signed: (b) (4) **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ◯
	No ⬤
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: [(b) (4)] **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	FLUTICASONE
Prophylaxis	Yes ◯
	No ⬤
Indication	IDIOPATHIC RHINITIS
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 ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: ████ (b) (4) ████ **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	TRIAMCINOLONE ACETONIDE CREAM

Prophylaxis	Yes	⚪
	No	⚫

Indication	DIFFUSE BULLOUS RASH (NON-URTICARIAL)

Dose per administration	1

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

If dose unit is Other, specify	APPLICATION

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

If frequency is Other, specify	

Route of administration	Oral	⚪
	Topical	⚫
	Subcutaneous	⚪
	Transdermal	⚪

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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)*	15 SEP 2020
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 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	CICLOPIROX CREAM
Prophylaxis	Yes ◯
	No ⬤
Indication	DIFFUSE BULLOUS RASH (NON-URTICARIAL)
Dose per administration	1
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	APPLICATION
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 (5)

Data signed: (b) (4) **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

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)*	15 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: ▓▓▓▓ (b) (4) ▓▓▓▓ **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	CLOBETASOL (0.05%)
Prophylaxis	Yes ⚪
	No ⚫
Indication	DIFFUSE BULLOUS RASH (NON-URTICARIAL)
Dose per administration	1
Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚫
If dose unit is Other, specify	APPLICATION
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)*	17 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)	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)   **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	ALLOPURINOL

Prophylaxis	Yes ⚪
	No ⚫

Indication	DIFFUSE BULLOUS RASH (NON-URTICARIAL)

Dose per administration	200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪

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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)*	24 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 OCT 2020
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) **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	HYDROXYZINE

Prophylaxis	Yes ○
	No ●

Indication	PRUITIS (ENTIRE BODY)
Dose per administration	25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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

If route of administration is Other, specify

Start date *(dd MMM yyyy)*

Start date completely unknown | True

Ongoing? | Yes ◯
| No ⬤

If not Ongoing, End date *(dd MMM yyyy)* | 02 OCT 2020

Was this medication taken for solicited event? | Yes ◯
| No ⬤

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived) | 802 ◯
| 803 ◯
| 804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: ⬛⬛⬛ (b) (4) ⬛⬛⬛ 25 Apr 2021 11:12:09

Generated On: 09 Jun 2021 17:37:11

Name of Medication	TYLENOL
Prophylaxis	Yes ⬤
	No ⬤
Indication	FEVER
Dose per administration	UNK
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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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)*	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4)   **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	CEFTRIAXONE

Prophylaxis   Yes ⚪
   No ⚫

Indication	RASH (DIFFUSE BULLOUS RASH NON-URTICARIAL)
Dose per administration	UNK

Dose unit

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

If dose unit is Other, specify	UNK

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)*	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: [(b) (4)] **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	LEVOTHYROXINE SODIUM

Prophylaxis

Yes ◯
No ⬤

Indication	HYPOTHYROIDISM
Dose per administration	75

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify   2X/WEEK

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

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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)*	
Start date completely unknown	True
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: [(b) (4)] **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

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

PRODUCTION RELEASE (v12.003
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)*	
Start date completely unknown	True
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
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)] **25 Apr 2021 11:12:09**

Generated On: 09 Jun 2021 17:37:11

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ◯
	No ⬤
Indication	RASH (DIFFUSE BULLOUS RASH NON-URTICARIAL)
Dose per administration	UNK
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ⬤
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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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)*	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 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 ◯

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: ░░░ (b) (4) ░░░ **19 Feb 2021 02:21:10**

Generated On: 09 Jun 2021 17:37:11

Were any concomitant procedures performed?   Yes ●

                                                             No ◯

If yes, please complete Concomitant Procedures form.

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **19 Feb 2021 02:21:10**

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
4 SEP 2020	AXILLARY BIOPSY	Medical History	
17 SEP 2020	SKIN BIOPSY	Adverse Event	
22 SEP 2020	MRI- NECK	Adverse Event	
22 SEP 2020	ULTRASOUND- NECK	Adverse Event	
30 SEP 2020	CT SCAN (CHEST, ABDOMEN, PELVIS)	Medical History	
17 SEP 2020	EKG	Medical History	
02 SEP 2020	CATARACT SURGERY	Medical History	

US3432295

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4)   **19 Feb 2021 02:21:10**

Generated On: 09 Jun 2021 17:37:11

Date of dosing discontinuation (dd MMM yyyy)	2 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

_____

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) **19 Feb 2021 02:21:10**

Generated On: 09 Jun 2021 17:37:11

Date of study discontinuation/completion *(dd MMM yyyy)*	2 OCT 2020

Reason for discontinuation	
AE (specify)	◯
SAE (specify)	◯
Complete	◯
Death	⬤
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	◯
Other	◯

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

If reason for discontinuation is Death, main cause of death	
Adverse event	⬤
Unknown	◯
Other	◯

If main cause of death is Other, specify

Date of death *(dd MMM yyyy)*	2 OCT 2020

Was autopsy performed?	
Yes	◯
No	◯
Unknown	⬤

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: [b] (4)   **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	22/SEP/2020 10:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:02
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-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	04/OCT/2020 08:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	05/OCT/2020 14:39
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

FDA-CBER-2022-1614-2604569

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: [(b) (4)] **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:44
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

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	22/OCT/2020 15:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4)   **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	26/OCT/2020 14:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4)   **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	02/NOV/2020 14:37
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

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	26/JAN/2021 12:47
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

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: [(b) (4)] **25 Apr 2021 11:12:10**

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	11/FEB/2021 13:01
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-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	08/APR/2021 09:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Data signed: (b) (4)   25 Apr 2021 11:12:10

Generated On: 09 Jun 2021 17:37:11

SAEID	USA-US078-2020-MRNA-1273-P30 1000002
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	13/APR/2021 10:31
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

US3432295 (Prod: Brigham and Womens Hospital)

US3432295

Form: Participant Creation

Generated On: 09 Jun 2021 17:37:11

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 02:33:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'US3432295'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:09:51

US3432295
Form: Participant Creation
Generated On: 09 Jun 2021 17:37:11

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:21

US3432295
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:37:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:09:52

US3432295

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Clinic (Clinic)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:21

US3432295
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:37:11
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'SCRN'	System	26 Aug 2020 14:27:21

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:37:11
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered (b) (6) 1936'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:09:53

US3432295
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:37:11

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '83'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:37:11
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'YEARS'	System	26 Aug 2020 15:06:18

US3432295
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:37:11

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '83'	System	26 Aug 2020 14:27:30

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Male (M)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '1'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:37:11
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:37:11
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:18

US3432295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:11

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:30

US3432295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:11

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Aug 2020'	System	26 Aug 2020 14:27:30

US3432295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:11

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '2020'	System	26 Aug 2020 14:27:30

US3432295
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:37:11
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Amendment 3 (3)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:30

US3432295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:11

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:30

US3432295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:30

US3432295

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:30

Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:37:11

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:30

US3432295
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:37:11
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:09:52

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '1'	System	26 Aug 2020 14:27:35

US3432295
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:37:11
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:35

US3432295

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:37:11

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:31:30

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:36:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Leukaemias, HLT: Leukaemias chronic lymphocytic, PT: Chronic lymphocytic leukaemia, LLT: Chronic lymphocytic leukemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:14:46
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 18:14:46
Data point term sent to Coder	System	26 Aug 2020 14:32:28
User entered 'Chronic lymphocytic leukemia (no therapy, monitored)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:36:43
User entered 'Un UNK 2019'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:36:44
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:36:46
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:36:48
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:36:49
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Jan 2019'	System	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '2019'	System	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:32:02

US3432295
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:32:02

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:36:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:36:49
Data point term sent to Coder	System	26 Aug 2020 14:35:37
User entered 'Hypothyroidism'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'UN UNK 2005'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Jan 2005'	System	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '2005'	System	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:00

US3432295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
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.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:36:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:36:49
Data point term sent to Coder	System	26 Aug 2020 14:35:37
User entered 'Benign prostatic hyperplasia'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:17

US3432295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Un UNK 2017'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:17

US3432295
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:37:11
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:17

US3432295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:17

US3432295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:17

US3432295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:17

US3432295

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Jan 2017'	System	26 Aug 2020 14:35:17

US3432295
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:37:11
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '2017'	System	26 Aug 2020 14:35:17

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:17

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:17

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:12:38
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 18:12:38
Data point term sent to Coder	System	26 Aug 2020 14:35:38
User entered 'Idiopathic Rhinitis'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'UN UNK 1990'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Jan 1990'	System	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '1990'	System	26 Aug 2020 14:35:30

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:30

US3432295
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:37:11
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:30

US3432295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:37:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:37:54
Data point term sent to Coder	System	26 Aug 2020 14:36:40
User entered 'Bradycardia'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:43

US3432295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'UN UNK 2000'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:43

US3432295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:43

US3432295
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:37:11
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:43

US3432295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:43

US3432295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:43

US3432295

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Jan 2000'	System	26 Aug 2020 14:35:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '2000'	System	26 Aug 2020 14:35:43

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US3432295
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:37:11
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 14:35:43

FDA-CBER-2022-1614-2604661

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:42:49
Data point term sent to Coder	System	02 Sep 2020 17:42:12
User entered 'Cataracts'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 23:34:31
User closed query 'per source MH log start date is 2020, please check edit source/EDC as required.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 23:34:27
Query 'per source MH log start date is 2020, please check edit source/EDC as required.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:20:25
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:19:11
User entered 'UN UNK 2020' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:19:11
User opened query 'per source MH log start date is 2020, please check edit source/EDC as required.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 17:38:10
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'Jan 2020'	System	25 Jan 2021 18:19:11
User entered 'Jan 2018'	System	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '2020'	System	25 Jan 2021 18:19:11
User entered '2018'	System	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	02 Sep 2020 17:41:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	02 Sep 2020 17:41:52

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Eye disorders congenital, HLT: Corneal and scleral disorders congenital, PT: Corneal dystrophy, LLT: Fuchs' endothelial dystrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:32
Data point term sent to Coder	System	14 Oct 2020 16:26:22
User entered 'Fuch's Dystrophy'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:24

US3432295
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:37:11
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:24

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:24

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:24

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:24

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:24

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:24

US3432295
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:37:11
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:24

US3432295

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:24

Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:24

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per DM CLR: Please update the condition to confirm if the CYST was benign or cancerous. 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)	02 Dec 2020 17:46:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
Query 'Per DM CLR: Please update the condition to confirm if the CYST was benign or cancerous. 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 'unable to obtain answer as participant has passed away. This was added post mortem from medical record' (Site from DM).	Monica Feeley (b) (4) (b) (4)	29 Oct 2020 13:35:23
User opened query 'Per DM CLR: Please update the condition to confirm if the CYST was benign or cancerous. 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)	28 Oct 2020 04:57:21
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Renal cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:32
Data point term sent to Coder	System	14 Oct 2020 16:26:22
User entered 'Renal Cyst'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:33

US3432295
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:37:11
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:33

US3432295
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:33

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:31
Data point term sent to Coder	System	14 Oct 2020 16:26:23
User entered 'CKD stage 3'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:42

US3432295
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:37:11
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:42

US3432295

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:42

US3432295
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:37:11
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:32
Data point term sent to Coder	System	14 Oct 2020 16:26:23
User entered 'OSA'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:50

US3432295

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:50

US3432295
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 17:37:11
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:00:43
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no medication' (Site from DM).	Monica Feeley (b) (4) (b) (4)	29 Oct 2020 13:35:38
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:58:04
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Open angle glaucoma, LLT: Open angle glaucoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:27:33
Data point term sent to Coder	System	14 Oct 2020 16:26:24
User entered 'Open angle glaucoma'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:58

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:58

FDA-CBER-2022-1614-2604713

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:58

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:58

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:58

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:25:58

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:58

US3432295
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:58

US3432295

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:58

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:25:58

FDA-CBER-2022-1614-2604721

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Site specific vascular disorders NEC, PT: Aortic dilatation, LLT: Aortic dilatation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:14:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 09:14:23
Data point term sent to Coder	System	14 Oct 2020 16:26:24
User entered 'Aortic Root Dilation'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:26:08

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	14 Oct 2020 16:26:08

US3432295

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Night sweats, LLT: Night sweats - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 13:55:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 13:55:15
Data point term sent to Coder	System	31 Oct 2020 13:54:45
User entered 'Night Sweats'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:54:14

US3432295

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:54:14

US3432295

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:54:14

US3432295

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:54:14

US3432295

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:54:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:54:14

US3432295
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:37:11
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:54:14

US3432295

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:54:14

US3432295
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:37:11
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:54:14

US3432295
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:37:11
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:54:14

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 15:42:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 15:42:21
Data point term sent to Coder	System	31 Oct 2020 13:58:46
User entered 'Right Axillary lympthodenopathy'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:37:11

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:22

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Pharyngeal disorders (excl infections and neoplasms), PT: Tonsillar hypertrophy, LLT: Tonsillar hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 12:21:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 12:21:51
Data point term sent to Coder	System	31 Oct 2020 13:58:46
User entered 'Soft Tissue Thickening in L Tonsillar fossa'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:38

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:38

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '1'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:38

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:38

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:38

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:37:34
User entered '0'	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:58:38

US3432295
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:37:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:38

US3432295
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:37:11
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:38

US3432295

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:37:11

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:38

US3432295
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:37:11
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	31 Oct 2020 13:58:38

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10:11'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '26 Aug 2020 10:11'	System	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '171' cm	Monica Feeley (b) (4)	26 Aug 2020 16:03:00
	(b) (4)	
DataPoint set to visible.	System	26 Aug 2020 14:27:35

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '68.4' kg	Monica Feeley (b) (4)	26 Aug 2020 16:03:00
DataPoint set to visible.	System	26 Aug 2020 14:27:35

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
Amendment Manager: User entered '23.39181'	System	17 Sep 2020 00:03:22
User entered '23.4'	System	26 Aug 2020 16:03:00
DataPoint set to visible.	System	26 Aug 2020 14:27:35

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'kg/m2'	System	26 Aug 2020 16:03:00
DataPoint set to visible.	System	26 Aug 2020 14:27:35

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'bpm'	System	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'breaths/min'	System	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'mmHg'	System	26 Aug 2020 16:03:00

US3432295

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:11

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'mmHg'	System	26 Aug 2020 16:03:00

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05

US3432295
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:37:11
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05

US3432295

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:54

US3432295

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:11

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:54

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:37:11
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'retired'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:37:11
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '1'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:37:11
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:11

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:05:57

US3432295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:43

US3432295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:43

US3432295

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Clinic (Clinic)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:43

US3432295
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:37:11
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'VISIT1'	System	26 Aug 2020 14:27:43

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:25:44

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '188217'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:25:44

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:25:44

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:31

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:31

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:31

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:06:31

US3432295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:11

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	23 Sep 2020 22:16:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:00:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:00:47

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:37:11

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User accepted default value 'Pre-Dose (PREDOSE)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10:11'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '26 Aug 2020 10:11'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '36.5' C	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Oral (Oral)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:37:11
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '046'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'bpm'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '012'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'breaths/min'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '123'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'mmHg'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 13:04:27
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jun Bai Park Chang (b) (4)	17 Sep 2020 13:47:47
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:03:22
User entered '057'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'mmHg'	System	26 Aug 2020 16:05:06

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US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered missing code ND - Not Done.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User accepted default value 'Post-Dose (POSTDOSE)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '11:42'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '26 Aug 2020 11:42'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '36.5' C	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Oral (Oral)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 19:52:04
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'non clinically significant' (Site from System).	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:23
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 16:05:06
User entered '044'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'bpm'	System	26 Aug 2020 16:05:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '014'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'breaths/min'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '124'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'mmHg'	System	26 Aug 2020 16:05:06

US3432295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 13:04:33
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jun Bai Park Chang (b) (4)	17 Sep 2020 13:47:59
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:03:22
User entered '058'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'mmHg'	System	26 Aug 2020 16:05:06

Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:37:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:48

US3432295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:11

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:27:48

US3432295
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:37:11
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:40:56

US3432295
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:37:11
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:40:56

US3432295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:40:56

US3432295
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:37:11
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:40:56

US3432295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:40:56

US3432295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '11:12'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:40:56

US3432295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '26 Aug 2020 11:12'	System	26 Aug 2020 15:40:56

US3432295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Left Arm (LEFT ARM)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 15:40:56

US3432295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'ONCE'	System	26 Aug 2020 15:40:56

US3432295
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:37:11
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:40:56

US3432295
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:37:11
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:25

US3432295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:25

US3432295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10:25'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:25

US3432295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '26 Aug 2020 10:25'	System	26 Aug 2020 16:29:25

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26 Aug 2020'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

US3432295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

US3432295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

US3432295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10:30'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

US3432295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '26 Aug 2020 10:30'	System	26 Aug 2020 16:29:52

US3432295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:11

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:37:11
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

US3432295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:29:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered empty.	System	26 Aug 2020 16:29:52

FDA-CBER-2022-1614-2604881

US3432295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 16:05:37

US3432295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '1'	System	26 Aug 2020 16:05:37

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:46:30', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'ebc0a671-e0a5-4a03-8f39-1263f25fdb7d'	System	26 Aug 2020 15:47:08
User entered 'Yes (Y)'	System	26 Aug 2020 15:47:08

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:46:44', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'ebc0a671-e0a5-4a03-8f39-1263f25fdb7d'	System	26 Aug 2020 15:47:08
User entered '97.7'	System	26 Aug 2020 15:47:08

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:46:50', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'ebc0a671-e0a5-4a03-8f39-1263f25fdb7d'	System	26 Aug 2020 15:47:08
User entered 'No (N)'	System	26 Aug 2020 15:47:08

FDA-CBER-2022-1614-2604887

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:47:04', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'ebc0a671-e0a5-4a03-8f39-1263f25fdb7d'	System	26 Aug 2020 15:47:08
User entered '26 Aug 2020 11:47'	System	26 Aug 2020 15:47:08

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 11:32'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 14:02'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:23:19', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'db6d5bf5-4ea1-4d12-b435-639b844f6d09'	System	27 Aug 2020 02:24:10
User entered 'Yes (Y)'	System	27 Aug 2020 02:24:10

FDA-CBER-2022-1614-2604892

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:23:34', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'db6d5bf5-4ea1-4d12-b435-639b844f6d09'	System	27 Aug 2020 02:24:10
User entered '97.7'	System	27 Aug 2020 02:24:10

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:23:39', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'db6d5bf5-4ea1-4d12-b435-639b844f6d09'	System	27 Aug 2020 02:24:10
User entered 'No (N)'	System	27 Aug 2020 02:24:10

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:23:53', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'db6d5bf5-4ea1-4d12-b435-639b844f6d09'	System	27 Aug 2020 02:24:10
User entered '26 Aug 2020 22:23'	System	27 Aug 2020 02:24:10

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 14:57'	System	26 Aug 2020 15:40:56

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

FDA-CBER-2022-1614-2604897

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 2'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:02:40', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '62c9a1b9-dd78-4b1b-93bd-4632e5ba0bfb'	System	28 Aug 2020 04:03:16
User entered 'Yes (Y)'	System	28 Aug 2020 04:03:16

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:02:55', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '62c9a1b9-dd78-4b1b-93bd-4632e5ba0bfb'	System	28 Aug 2020 04:03:16
User entered '96.7'	System	28 Aug 2020 04:03:16

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:03', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '62c9a1b9-dd78-4b1b-93bd-4632e5ba0bfb'	System	28 Aug 2020 04:03:16
User entered 'No (N)'	System	28 Aug 2020 04:03:16

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:12', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '62c9a1b9-dd78-4b1b-93bd-4632e5ba0bfb'	System	28 Aug 2020 04:03:16
User entered '28 Aug 2020 00:03'	System	28 Aug 2020 04:03:16

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 3'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:30:40', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '5cc97f6d-4416-474d-8361-6573fa738979'	System	29 Aug 2020 02:31:08
User entered 'Yes (Y)'	System	29 Aug 2020 02:31:08

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:30:49', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '5cc97f6d-4416-474d-8361-6573fa738979'	System	29 Aug 2020 02:31:08
User entered '97.4'	System	29 Aug 2020 02:31:08

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:30:55', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '5cc97f6d-4416-474d-8361-6573fa738979'	System	29 Aug 2020 02:31:08
User entered 'No (N)'	System	29 Aug 2020 02:31:08

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:37:11
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:04', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '5cc97f6d-4416-474d-8361-6573fa738979'	System	29 Aug 2020 02:31:08
User entered '28 Aug 2020 22:31'	System	29 Aug 2020 02:31:08

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 4'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:10', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9667c72a-e244-42e6-84fb-287e155e854d'	System	30 Aug 2020 02:05:40
User entered 'Yes (Y)'	System	30 Aug 2020 02:05:40

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:19', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9667c72a-e244-42e6-84fb-287e155e854d'	System	30 Aug 2020 02:05:40
User entered '98.0'	System	30 Aug 2020 02:05:40

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:25', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9667c72a-e244-42e6-84fb-287e155e854d'	System	30 Aug 2020 02:05:40
User entered 'No (N)'	System	30 Aug 2020 02:05:40

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:38', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9667c72a-e244-42e6-84fb-287e155e854d'	System	30 Aug 2020 02:05:40
User entered '29 Aug 2020 22:05'	System	30 Aug 2020 02:05:40

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 5'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:37:11
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:34:27', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '53549f56-3f8d-4501-93a2-44936fda65c2'	System	31 Aug 2020 02:34:57
User entered 'Yes (Y)'	System	31 Aug 2020 02:34:57

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:34:41', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '53549f56-3f8d-4501-93a2-44936fda65c2'	System	31 Aug 2020 02:34:57
User entered '97.6'	System	31 Aug 2020 02:34:57

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:34:46', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '53549f56-3f8d-4501-93a2-44936fda65c2'	System	31 Aug 2020 02:34:57
User entered 'No (N)'	System	31 Aug 2020 02:34:57

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:34:54', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '53549f56-3f8d-4501-93a2-44936fda65c2'	System	31 Aug 2020 02:34:57
User entered '30 Aug 2020 22:34'	System	31 Aug 2020 02:34:57

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:37:11
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 6'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:39:49', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '33fa3d0c-c896-48c1-ac33-ffa5bbeb4b7a'	System	01 Sep 2020 02:40:13
User entered 'Yes (Y)'	System	01 Sep 2020 02:40:13

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:39:57', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '33fa3d0c-c896-48c1-ac33-ffa5bbeb4b7a'	System	01 Sep 2020 02:40:13
User entered '98.7'	System	01 Sep 2020 02:40:13

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:01', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '33fa3d0c-c896-48c1-ac33-ffa5bbeb4b7a'	System	01 Sep 2020 02:40:13
User entered 'No (N)'	System	01 Sep 2020 02:40:13

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:09', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '33fa3d0c-c896-48c1-ac33-ffa5bbeb4b7a'	System	01 Sep 2020 02:40:13
User entered '31 Aug 2020 22:40'	System	01 Sep 2020 02:40:13

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:37:11
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 7'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:09:30', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '40391930-dc07-4b58-84dd-ebae3f820fcf'	System	02 Sep 2020 02:09:51
User entered 'Yes (Y)'	System	02 Sep 2020 02:09:51

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:37:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:09:39', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '40391930-dc07-4b58-84dd-ebae3f820fcf'	System	02 Sep 2020 02:09:51
User entered '99.1'	System	02 Sep 2020 02:09:51

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:09:44', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '40391930-dc07-4b58-84dd-ebae3f820fcf'	System	02 Sep 2020 02:09:51
User entered 'No (N)'	System	02 Sep 2020 02:09:51

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:09:49', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '40391930-dc07-4b58-84dd-ebae3f820fcf'	System	02 Sep 2020 02:09:51
User entered '01 Sep 2020 22:09'	System	02 Sep 2020 02:09:51

US3432295
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:37:11
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:47:20', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'bba4c162-c6bb-4891-9341-cf9630b1a2c4'	System	26 Aug 2020 15:48:03
User entered 'None (1)'	System	26 Aug 2020 15:48:03

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:47:31', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'bba4c162-c6bb-4891-9341-cf9630b1a2c4'	System	26 Aug 2020 15:48:03
User entered 'No (N)'	System	26 Aug 2020 15:48:03

FDA-CBER-2022-1614-2604942

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:47:36', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'bba4c162-c6bb-4891-9341-cf9630b1a2c4'	System	26 Aug 2020 15:48:03
User entered 'No (N)'	System	26 Aug 2020 15:48:03

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:47:45', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'bba4c162-c6bb-4891-9341-cf9630b1a2c4'	System	26 Aug 2020 15:48:03
User entered 'None (1)'	System	26 Aug 2020 15:48:03

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:47:58', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'bba4c162-c6bb-4891-9341-cf9630b1a2c4'	System	26 Aug 2020 15:48:03
User entered '26 Aug 2020 11:47'	System	26 Aug 2020 15:48:03

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 11:32'	System	26 Aug 2020 15:40:56

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 14:02'	System	26 Aug 2020 15:40:56

FDA-CBER-2022-1614-2604947

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:24:07', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0402e88a-4ae1-4e76-ace0-f252efc1b5e0'	System	27 Aug 2020 02:24:47
User entered 'None (1)'	System	27 Aug 2020 02:24:47

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:24:11', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0402e88a-4ae1-4e76-ace0-f252efc1b5e0'	System	27 Aug 2020 02:24:47
User entered 'No (N)'	System	27 Aug 2020 02:24:47

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:24:16', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0402e88a-4ae1-4e76-ace0-f252efc1b5e0'	System	27 Aug 2020 02:24:47
User entered 'No (N)'	System	27 Aug 2020 02:24:47

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:24:31', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0402e88a-4ae1-4e76-ace0-f252efc1b5e0'	System	27 Aug 2020 02:24:47
User entered 'None (1)'	System	27 Aug 2020 02:24:47

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:24:44', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0402e88a-4ae1-4e76-ace0-f252efc1b5e0'	System	27 Aug 2020 02:24:47
User entered '26 Aug 2020 22:24'	System	27 Aug 2020 02:24:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 14:57'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 2'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:20', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '6d09ecd6-aedb-4895-9658-dc9d785c9e77'	System	28 Aug 2020 04:03:57
User entered 'None (1)'	System	28 Aug 2020 04:03:57

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:25', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '6d09ecd6-aedb-4895-9658-dc9d785c9e77'	System	28 Aug 2020 04:03:57
User entered 'No (N)'	System	28 Aug 2020 04:03:57

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:29', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '6d09ecd6-aedb-4895-9658-dc9d785c9e77'	System	28 Aug 2020 04:03:57
User entered 'No (N)'	System	28 Aug 2020 04:03:57

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:44', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '6d09ecd6-aedb-4895-9658-dc9d785c9e77'	System	28 Aug 2020 04:03:57
User entered 'None (1)'	System	28 Aug 2020 04:03:57

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:03:54', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '6d09ecd6-aedb-4895-9658-dc9d785c9e77'	System	28 Aug 2020 04:03:57
User entered '28 Aug 2020 00:03'	System	28 Aug 2020 04:03:57

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 3'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:14', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3aceb448-0ff0-4f7c-9547-9a0536c5042c'	System	29 Aug 2020 02:32:04
User entered 'None (1)'	System	29 Aug 2020 02:32:04

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:18', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3aceb448-0ff0-4f7c-9547-9a0536c5042c'	System	29 Aug 2020 02:32:04
User entered 'No (N)'	System	29 Aug 2020 02:32:04

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:23', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3aceb448-0ff0-4f7c-9547-9a0536c5042c'	System	29 Aug 2020 02:32:04
User entered 'No (N)'	System	29 Aug 2020 02:32:04

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:30', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3aceb448-0ff0-4f7c-9547-9a0536c5042c'	System	29 Aug 2020 02:32:04
User entered 'None (1)'	System	29 Aug 2020 02:32:04

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:46', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3aceb448-0ff0-4f7c-9547-9a0536c5042c'	System	29 Aug 2020 02:32:04
User entered '28 Aug 2020 22:31'	System	29 Aug 2020 02:32:04

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 4'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:46', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'b5a7a5fd-da2e-4b0d-901f-4fa0aeb6c696'	System	30 Aug 2020 02:06:09
User entered 'None (1)'	System	30 Aug 2020 02:06:09

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:51', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'b5a7a5fd-da2e-4b0d-901f-4fa0aeb6c696'	System	30 Aug 2020 02:06:09
User entered 'No (N)'	System	30 Aug 2020 02:06:09

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:05:54', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'b5a7a5fd-da2e-4b0d-901f-4fa0aeb6c696'	System	30 Aug 2020 02:06:09
User entered 'No (N)'	System	30 Aug 2020 02:06:09

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:00', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'b5a7a5fd-da2e-4b0d-901f-4fa0aeb6c696'	System	30 Aug 2020 02:06:09
User entered 'None (1)'	System	30 Aug 2020 02:06:09

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:06', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'b5a7a5fd-da2e-4b0d-901f-4fa0aeb6c696'	System	30 Aug 2020 02:06:09
User entered '29 Aug 2020 22:06'	System	30 Aug 2020 02:06:09

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 5'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:02', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3a6a63f7-a398-4bb4-81b9-de58727fcd00'	System	31 Aug 2020 02:35:31
User entered 'None (1)'	System	31 Aug 2020 02:35:31

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:08', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3a6a63f7-a398-4bb4-81b9-de58727fcd00'	System	31 Aug 2020 02:35:31
User entered 'No (N)'	System	31 Aug 2020 02:35:31

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:12', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3a6a63f7-a398-4bb4-81b9-de58727fcd00'	System	31 Aug 2020 02:35:31
User entered 'No (N)'	System	31 Aug 2020 02:35:31

FDA-CBER-2022-1614-2604983

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:18', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3a6a63f7-a398-4bb4-81b9-de58727fcd00'	System	31 Aug 2020 02:35:31
User entered 'None (1)'	System	31 Aug 2020 02:35:31

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:28', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3a6a63f7-a398-4bb4-81b9-de58727fcd00'	System	31 Aug 2020 02:35:31
User entered '30 Aug 2020 22:35'	System	31 Aug 2020 02:35:31

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:37:11
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 6'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:15', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '602443fa-a32e-4e49-a700-e893e0b05c0e'	System	01 Sep 2020 02:40:40
User entered 'None (1)'	System	01 Sep 2020 02:40:40

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:19', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '602443fa-a32e-4e49-a700-e893e0b05c0e'	System	01 Sep 2020 02:40:40
User entered 'No (N)'	System	01 Sep 2020 02:40:40

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:23', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '602443fa-a32e-4e49-a700-e893e0b05c0e'	System	01 Sep 2020 02:40:40
User entered 'No (N)'	System	01 Sep 2020 02:40:40

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:28', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '602443fa-a32e-4e49-a700-e893e0b05c0e'	System	01 Sep 2020 02:40:40
User entered 'None (1)'	System	01 Sep 2020 02:40:40

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:36', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '602443fa-a32e-4e49-a700-e893e0b05c0e'	System	01 Sep 2020 02:40:40
User entered '31 Aug 2020 22:40'	System	01 Sep 2020 02:40:40

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

FDA-CBER-2022-1614-2604994

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 7'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:09:59', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '361d02b5-84d2-4048-b753-284307884dd3'	System	02 Sep 2020 02:10:34
User entered 'None (1)'	System	02 Sep 2020 02:10:34

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:05', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '361d02b5-84d2-4048-b753-284307884dd3'	System	02 Sep 2020 02:10:34
User entered 'No (N)'	System	02 Sep 2020 02:10:34

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:09', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '361d02b5-84d2-4048-b753-284307884dd3'	System	02 Sep 2020 02:10:34
User entered 'No (N)'	System	02 Sep 2020 02:10:34

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:14', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '361d02b5-84d2-4048-b753-284307884dd3'	System	02 Sep 2020 02:10:34
User entered 'None (1)'	System	02 Sep 2020 02:10:34

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:27', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '361d02b5-84d2-4048-b753-284307884dd3'	System	02 Sep 2020 02:10:34
User entered '01 Sep 2020 22:10'	System	02 Sep 2020 02:10:34

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:48:11', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'None (0)'	System	26 Aug 2020 15:49:10

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:48:20', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'None (0)'	System	26 Aug 2020 15:49:10

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:48:30', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'None (0)'	System	26 Aug 2020 15:49:10

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:48:48', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'None (0)'	System	26 Aug 2020 15:49:10

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:48:51', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'None (0)'	System	26 Aug 2020 15:49:10

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:48:55', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'None (0)'	System	26 Aug 2020 15:49:10

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:49:00', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered 'No (N)'	System	26 Aug 2020 15:49:10

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T11:49:07', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '9ef203e4-a703-45c1-a0e5-afc141982a1d'	System	26 Aug 2020 15:49:10
User entered '26 Aug 2020 11:49'	System	26 Aug 2020 15:49:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 11:32'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 14:02'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:00', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'None (0)'	System	27 Aug 2020 02:25:38

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:03', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'None (0)'	System	27 Aug 2020 02:25:38

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:09', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'None (0)'	System	27 Aug 2020 02:25:38

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:15', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'None (0)'	System	27 Aug 2020 02:25:38

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:18', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'None (0)'	System	27 Aug 2020 02:25:38

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:21', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'None (0)'	System	27 Aug 2020 02:25:38

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:30', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered 'No (N)'	System	27 Aug 2020 02:25:38

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-26T22:25:36', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '79623b4e-c5ea-49ea-96f2-8effaa2f9a7e'	System	27 Aug 2020 02:25:38
User entered '26 Aug 2020 22:25'	System	27 Aug 2020 02:25:38

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '26 Aug 2020 14:57'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 2'	System	26 Aug 2020 15:40:56

FDA-CBER-2022-1614-2605026

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:37:11
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:06', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'None (0)'	System	28 Aug 2020 04:04:41

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:10', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'None (0)'	System	28 Aug 2020 04:04:41

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:15', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'None (0)'	System	28 Aug 2020 04:04:41

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:21', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'None (0)'	System	28 Aug 2020 04:04:41

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:24', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'None (0)'	System	28 Aug 2020 04:04:41

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:26', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'None (0)'	System	28 Aug 2020 04:04:41

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:32', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered 'No (N)'	System	28 Aug 2020 04:04:41

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:37:11
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T00:04:37', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '08c9df74-50b4-479b-9bee-dae067e36b06'	System	28 Aug 2020 04:04:41
User entered '28 Aug 2020 00:04'	System	28 Aug 2020 04:04:41

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 3'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:37:11
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:31:56', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'None (0)'	System	29 Aug 2020 02:32:25

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:00', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'None (0)'	System	29 Aug 2020 02:32:25

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:37:11
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:04', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'None (0)'	System	29 Aug 2020 02:32:25

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:37:11
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:08', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'None (0)'	System	29 Aug 2020 02:32:25

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:11', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'None (0)'	System	29 Aug 2020 02:32:25

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:13', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'None (0)'	System	29 Aug 2020 02:32:25

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:18', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered 'No (N)'	System	29 Aug 2020 02:32:25

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-28T22:32:24', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '3b66e2ff-fe66-4877-b29f-a7af12f82c4f'	System	29 Aug 2020 02:32:25
User entered '28 Aug 2020 22:32'	System	29 Aug 2020 02:32:25

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 4'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:12', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'None (0)'	System	30 Aug 2020 02:07:03

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:33', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'No interference with activity (1)'	System	30 Aug 2020 02:07:03

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:36', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'None (0)'	System	30 Aug 2020 02:07:03

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:40', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'None (0)'	System	30 Aug 2020 02:07:03

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:43', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'None (0)'	System	30 Aug 2020 02:07:03

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:48', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'None (0)'	System	30 Aug 2020 02:07:03

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:06:52', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered 'No (N)'	System	30 Aug 2020 02:07:03

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-29T22:07:02', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0579436b-a462-4f2f-aac2-1bf0f908abe6'	System	30 Aug 2020 02:07:03
User entered '29 Aug 2020 22:07'	System	30 Aug 2020 02:07:03

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:37:11
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 5'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:37:11
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:36', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'None (0)'	System	31 Aug 2020 02:36:20

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:40', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'None (0)'	System	31 Aug 2020 02:36:20

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:43', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'None (0)'	System	31 Aug 2020 02:36:20

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:35:50', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'None (0)'	System	31 Aug 2020 02:36:20

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:36:01', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'None (0)'	System	31 Aug 2020 02:36:20

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:36:04', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'None (0)'	System	31 Aug 2020 02:36:20

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:36:10', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered 'No (N)'	System	31 Aug 2020 02:36:20

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-30T22:36:18', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'e9f4cba2-d37d-4756-ad11-449daf44f3ba'	System	31 Aug 2020 02:36:20
User entered '30 Aug 2020 22:36'	System	31 Aug 2020 02:36:20

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 6'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:37:11
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:42', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'None (0)'	System	01 Sep 2020 02:41:24

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:50', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'None (0)'	System	01 Sep 2020 02:41:24

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:55', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'None (0)'	System	01 Sep 2020 02:41:24

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:40:59', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'None (0)'	System	01 Sep 2020 02:41:24

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:41:03', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'None (0)'	System	01 Sep 2020 02:41:24

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:41:06', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'None (0)'	System	01 Sep 2020 02:41:24

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:41:11', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered 'No (N)'	System	01 Sep 2020 02:41:24

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-08-31T22:41:19', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'cacf1fc4-d280-491e-9f5f-075692e7bc4d'	System	01 Sep 2020 02:41:24
User entered '31 Aug 2020 22:41'	System	01 Sep 2020 02:41:24

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	26 Aug 2020 15:40:56
User entered 'Day 7'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:33', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'None (0)'	System	02 Sep 2020 02:11:26

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:37', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'None (0)'	System	02 Sep 2020 02:11:26

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:10:50', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'No interference with activity (1)'	System	02 Sep 2020 02:11:26

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:11:00', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'None (0)'	System	02 Sep 2020 02:11:26

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:11:03', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'None (0)'	System	02 Sep 2020 02:11:26

US3432295
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:37:11
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:11:11', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'None (0)'	System	02 Sep 2020 02:11:26

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:11:15', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered 'No (N)'	System	02 Sep 2020 02:11:26

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-01T22:11:20', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '51bd7d83-8b7e-4405-a377-44f39883880a'	System	02 Sep 2020 02:11:26
User entered '01 Sep 2020 22:11'	System	02 Sep 2020 02:11:26

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:40:56

US3432295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:40:56

US3432295
Folder: Diary Dose 1 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	02 Sep 2020 02:11:26
User entered 'Day 8'	System	02 Sep 2020 02:11:26

US3432295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-02T21:59:48', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'd72e7e73-655a-41b7-9c11-a0586ba8db46'	System	03 Sep 2020 02:00:13
User entered 'None (0)'	System	03 Sep 2020 02:00:13

US3432295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-02T21:59:59', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: 'd72e7e73-655a-41b7-9c11-a0586ba8db46'	System	03 Sep 2020 02:00:13
User entered '02 Sep 2020 21:59'	System	03 Sep 2020 02:00:13

US3432295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 02:11:26

US3432295

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:11

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 02:11:26

US3432295
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:37:11
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
Data entry locked.	System	02 Sep 2020 02:11:26
User entered 'Day 8'	System	02 Sep 2020 02:11:26

US3432295
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-02T22:00:09', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0e476a08-af89-4020-a678-0e23a7a7906c'	System	03 Sep 2020 02:00:17
User entered 'No (N)'	System	03 Sep 2020 02:00:17

US3432295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:11

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0421737207afe365)', Time: '2020-09-02T22:00:15', User OID: 'PatientReportedOutcome (US3432295)', ODM File OID: '0e476a08-af89-4020-a678-0e23a7a7906c'	System	03 Sep 2020 02:00:17
User entered '02 Sep 2020 22:00'	System	03 Sep 2020 02:00:17

US3432295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 02:11:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:59:14
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 02:11:26

US3432295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:38:58

US3432295
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:37:11
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '02 Sep 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:11:39
User entered '2 Sep 2020'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:38:58

US3432295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:38:58

US3432295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	Phoebe Cunningham (b) (4)	02 Sep 2020 17:38:58

US3432295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:39:01

US3432295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '1'	System	02 Sep 2020 17:39:01

US3432295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 16:48:53

US3432295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '09 Sep 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:10:50
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:48:53

US3432295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 16:48:53

US3432295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 16:48:53

US3432295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 12:58:56

US3432295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '1'	System	16 Sep 2020 12:58:56

US3432295
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:37:11

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User closed query 'Per CDM: Please complete the eCRF pages (visit date and exposure) under Visit 2. Note: If the visit not performed, a response 'NO' can be provided. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:11:08
Query 'Per CDM: Please complete the eCRF pages (visit date and exposure) under Visit 2. Note: If the visit not performed, a response 'NO' can be provided. ' answered with 'Please see update' (Site from DM).	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:27:14
User opened query 'Per CDM: Please complete the eCRF pages (visit date and exposure) under Visit 2. Note: If the visit not performed, a response 'NO' can be provided. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 07:29:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 13:11:27

US3432295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 13:11:27

US3432295
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:37:11
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 13:11:27

US3432295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:11

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 13:11:27

US3432295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	10 Nov 2020 15:11:50

US3432295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:15:05
User entered '1'	System	10 Nov 2020 15:11:50

US3432295
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:37:11
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Tenaizus Woods (b) (4) (b) (4)	05 Mar 2021 18:25:43

US3432295
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:37:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	05 Mar 2021 18:25:43

US3432295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	05 Mar 2021 18:25:43

US3432295
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:37:11
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered 'VISIT2'	System	05 Mar 2021 18:25:43

US3432295
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:37:11

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User accepted default value 'Pre-Dose (PREDOSE)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

FDA-CBER-2022-1614-2605128

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:37:11
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:11

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

FDA-CBER-2022-1614-2605139

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User accepted default value 'Post-Dose (POSTDOSE)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:37:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:37:11
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:37:11

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

FDA-CBER-2022-1614-2605149

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

US3432295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:11

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:25:26

FDA-CBER-2022-1614-2605155

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:37:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:25:31

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	09 Mar 2021 21:26:36
User entered 'Death (DEATH)' reason for change: Data Entry Error	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:36
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	09 Mar 2021 21:26:19
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:19

US3432295
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:37:11

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:19

US3432295
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:37:11
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:19

US3432295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:42

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:42

US3432295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:42

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:11

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Megan Powell (b) (4) (b) (4)	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	09 Mar 2021 21:26:51

US3432295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:11

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Tenaizus Woods (b) (4) (b) (4)	05 Mar 2021 18:25:51

US3432295
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:37:11
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:23
User entered empty.	System	05 Mar 2021 18:25:51

US3432295

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

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	03 May 2021 15:24:40
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 May 2021 06:43:36
Query 'Data is required. Please complete.' answered with 'per query, delete data.' (Site from System).	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 17:33:17
Signature has been broken.	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:17
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:02

FDA-CBER-2022-1614-2605183

US3432295

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

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:02

US3432295

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

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:02

US3432295

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

Form: Visit Date

Generated On: 09 Jun 2021 17:37:11

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	29 Apr 2021 17:33:17
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 22:13:02

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered '0' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered '1'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 07:33:17
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Query 'Data is required. Please complete.' answered with 'per query, delete all data' (Site from System).	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:24:06
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:37:11

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'Amendment 5 (Amendment 5)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User closed query 'Per CDM re-query: Per previous query, please remove data from the rest of the pages at this visit so that they can be inactivated.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 06:44:54
Query 'Per CDM re-query: Per previous query, please remove data from the rest of the pages at this visit so that they can be inactivated.' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:35:03
User opened query 'Per CDM re-query: Per previous query, please remove data from the rest of the pages at this visit so that they can be inactivated.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:56:25
User closed query 'Per CDM: Re-query, response noted. As per sponsor, the PDV did not occur, all data should be removed from the PDV for inactivation. Please agree to remove all data so that the pages can be inactivated. Please note, all system queries that are generated will be closed and the pages will be inactivated. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:33:15
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Query 'Per CDM: Re-query, response noted. As per sponsor, the PDV did not occur, all data should be removed from the PDV for inactivation. Please agree to remove all data so that the pages can be inactivated. Please note, all system queries that are generated will be closed and the pages will be inactivated. ' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:20
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'Per CDM: Re-query, response noted. As per sponsor, the PDV did not occur, all data should be removed from the PDV for inactivation. Please agree to remove all data so that the pages can be inactivated. Please note, all system queries that are generated will be closed and the pages will be inactivated. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:42:52
User closed query ' Per CDM: The Study discontinuation date is prior to the date of Unblinding in IRT. Please confirm the subject was discontinued before unblinding. If correct, please agree to remove all data from the unblinding form and PVD as appropriate, or else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:42:52
Query ' Per CDM: The Study discontinuation date is prior to the date of Unblinding in IRT. Please confirm the subject was discontinued before unblinding. If correct, please agree to remove all data from the unblinding form and PVD as appropriate, or else clarify.' answered with 'data is still relevant and should be entered. ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	22 Apr 2021 21:04:43
User opened query ' Per CDM: The Study discontinuation date is prior to the date of Unblinding in IRT. Please confirm the subject was discontinued before unblinding. If correct, please agree to remove all data from the unblinding form and PVD as appropriate, or else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:52:52
User closed query 'Per CDM: Date of unblinding is after date of study discontinuation. Please clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:52:44
Query 'Per CDM: Date of unblinding is after date of study discontinuation. Please clarify. ' answered with 'Participant died in October. Thus, they were unable to be unblinded before study termination' (Site from DM).	Julia Klopfer (b) (4) (b) (4)	12 Apr 2021 13:03:17
User opened query 'Per CDM: Date of unblinding is after date of study discontinuation. Please clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 15:31:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered '3 Dec 2020'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'Placebo (Placebo)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:37:11

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'Placebo (Placebo)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'Placebo (Placebo)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	28 Apr 2021 21:59:25
Signature has been broken.	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	28 Apr 2021 16:24:06
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	28 Apr 2021 16:24:06
User entered '1'	System	31 Mar 2021 22:13:24

US3432295

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

Form: Unblinding

Generated On: 09 Jun 2021 17:37:11

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	31 Mar 2021 22:13:24

US3432295

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	03 May 2021 15:24:40
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 May 2021 06:43:49
Query 'Data is required. Please complete.' answered with 'per query, delete' (Site from System).	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:39
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 17:33:33
Signature has been broken.	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:33
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:29

FDA-CBER-2022-1614-2605199

US3432295

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:29

US3432295

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	31 Mar 2021 22:13:29

FDA-CBER-2022-1614-2605202

US3432295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:11

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	03 May 2021 15:24:40
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 May 2021 06:44:00
Query 'Data is required. Please complete.' answered with 'per query, delete' (Site from System).	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:54
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 17:33:46
Signature has been broken.	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:46
User entered empty; reason for change Data Entry Error	Jun Bai Park Chang (b) (4)	29 Apr 2021 17:33:46
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:33

US3432295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:11

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:33

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:37:11
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:47:43
User entered empty.	Jessica Cauley (b) (4) (b) (4)	31 Mar 2021 22:13:33

US3432295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:11

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	31 Mar 2021 22:13:33

FDA-CBER-2022-1614-2605206

US3432295
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:37:11

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per CDM Re-Query: response is noted; however, please review as primary cause of death should be recorded as fatal.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:51:19
Query 'Per CDM Re-Query: response is noted; however, please review as primary cause of death should be recorded as fatal.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:42:37
User opened query 'Per CDM Re-Query: response is noted; however, please review as primary cause of death should be recorded as fatal.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:36:25
User closed query 'Per CDM: Only one (the primary) AE should be recorded as Fatal. Please review the two AEs recorded and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:36:25
Query 'Per CDM: Only one (the primary) AE should be recorded as Fatal. Please review the two AEs recorded and update accordingly.' answered with 'both marked as fatal because they are intertwined. Also, rash was not resolved at time of death so this is appropriate response.' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:37:07
User opened query 'Per CDM: Only one (the primary) AE should be recorded as Fatal. Please review the two AEs recorded and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:22:46
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 18:55:35
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:15:32

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:18
User entered 'USA-US078-2020-mRNA-1273-P301000002'	System	22 Sep 2020 14:27:14
User entered 'New'	(b) (4), (b) (6)	22 Sep 2020 14:27:14

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 03:33:08
User closed query 'Per DM CLR: Please review AE and please update to indicate whether the reported rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:44:22
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Bullous conditions, PT: Dermatitis bullous, LLT: Bullous rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 20:32:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 20:32:24
Data point term sent to Coder	System	31 Oct 2020 12:56:19
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 12:55:46
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 12:55:46
User entered 'DIFFUSE BULLOUS RASH (non-urticarial)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 12:55:46
Query 'Per DM CLR: Please review AE and please update to indicate whether the reported rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'non-urticarial ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 12:55:34
User opened query 'Per DM CLR: Please review AE and please update to indicate whether the reported rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 23:32:35
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Bullous conditions, PT: Dermatitis bullous, LLT: Bullous rash - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	07 Oct 2020 16:14:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	07 Oct 2020 16:14:08
User closed query 'PV Query: Please consider updating event term to final diagnosis. If current event term is to remain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:32:17
Data point term sent to Coder	System	02 Oct 2020 20:20:07
Query 'PV Query: Please consider updating event term to final diagnosis. If current event term is to remain, please state so.' answered with 'updated term' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:19:44
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:19:36
User entered 'diffuse bullous rash' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:19:36
User opened query 'PV Query: Please consider updating event term to final diagnosis. If current event term is to remain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:33:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Bullous conditions, PT: Blister, LLT: Blisters - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	17 Sep 2020 22:18:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	17 Sep 2020 22:18:29
Data point term sent to Coder	System	17 Sep 2020 22:17:25
User entered 'Blisters'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '12 Sep 2020'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	17 Sep 2020 22:16:29

US3432295
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
Signature has been broken.	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:27:54
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
Signature has been broken.	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
User entered empty; reason for change New Information	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:32:33
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Oct 2020 17:27:54
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	03 Oct 2020 17:27:54
User entered '02 Oct 2020' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:27:54
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Oct 2020 17:27:02
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'event is ongoing currently' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:20:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:32:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	03 Oct 2020 17:28:19
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:28:19
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	03 Oct 2020 17:27:02
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Yes (Y)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:42:31
Signature has been broken.	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:42:31
User entered '0' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:42:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '1' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:54
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
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)	23 Sep 2020 08:14:00
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 'admission date filed in, as well as not admitted to ICU. Not discharged yet.' (Site from System).	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:11:29
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	21 Sep 2020 23:10:56
User entered '1' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '17 Sep 2020' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:02:39
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'discharged on 9/24/2020' (Site from Safety).	Xhoi Mitre (b) (4) (b) (4)	01 Oct 2020 17:37:27
User entered '24 Sep 2020' reason for change: New Information	Xhoi Mitre (b) (4) (b) (4)	01 Oct 2020 17:37:04
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:32:42
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered 'None (NONE)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:03:28
User entered '1'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '1' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:03:28
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per CDM: Per CCG Guidelines, Page 52, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please review and update appropriately. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:36:22
Query 'Per CDM: Per CCG Guidelines, Page 52, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please review and update appropriately. ' answered with 'we have updated this to not recovered/not resolved. however, we will keep getting queries that the AE is open. and we are being told to close all AEs. so not sure what to do here' (Site from DM).	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:23:50
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
Signature has been broken.	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	12 Apr 2021 20:22:33
User opened query 'Per CDM: Per CCG Guidelines, Page 52, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please review and update appropriately. ' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 07:19:39
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18

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Folder: Adverse Events
Form: Adverse Events (1)
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Outcome

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	04 Oct 2020 12:32:45
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 'Fatal' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:28:10
User entered 'Fatal (FATAL)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:27:02
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 Sep 2020 19:31:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per DM CLR: SAE Narrative indicates Worsening Night Sweats, Fatigue, B-Cell Lymphoproliferative Disorder, Soft Tissue Thickening in Left Tonsillar Fossa, Right Axillary and Supraclavicular Lymphadenopathy were all noted. However, there is no corresponding AE record to match the information. Please update to record the corresponding AEs as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:41:21
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had Complete Blood Count and Blood Chemistry exam. However, there are no corresponding ConProc record to match these information. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:28:17
Query 'Per DM CLR: SAE Narrative indicates Worsening Night Sweats, Fatigue, B-Cell Lymphoproliferative Disorder, Soft Tissue Thickening in Left Tonsillar Fossa, Right Axillary and Supraclavicular Lymphadenopathy were all noted. However, there is no corresponding AE record to match the information. Please update to record the corresponding AEs as applicable. Otherwise, clarify.' answered with 'we retrospectively learned that participant was having night sweats and fatigue prior to enrollment. We will capture as medical history. We retrospectively learned that soft Tissue Thickening in Left Tonsillar Fossa was present prior to enrollment. We will capture as medical history. We retrospectively learned that Right Axillary Lymphadenopathy was present prior to enrollment. We will capture as medical history. B-Cell Lymphoproliferative Disorder is pre-existing (CLL). Already captured in med history. Supraclavicular Lymphadenopathy will be added as AE. ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:23:03

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Folder: Adverse Events
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Narrative

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative indicates that the subject had Complete Blood Count and Blood Chemistry exam. However, there are no corresponding ConProc record to match these information. Please update as appropriate or provide clarification.' answered with 'these are blood draws, do not need to be added to procedure' (Site from DM).	Monica Feeley (b) (4) (b) (4)	29 Oct 2020 13:36:36
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had Complete Blood Count and Blood Chemistry exam. However, there are no corresponding ConProc record to match these information. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 23:33:46
User opened query 'Per DM CLR: SAE Narrative indicates Worsening Night Sweats, Fatigue, B-Cell Lymphoproliferative Disorder, Soft Tissue Thickening in Left Tonsillar Fossa, Right Axillary and Supraclavicular Lymphadenopathy were all noted. However, there is no corresponding AE record to match the information. Please update to record the corresponding AEs as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 23:33:19
Query 'PV Query: Please provide clinical consultant reports.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:12:17
Query 'PV Query: Please provide pathology, laboratory and imaging reports.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:12:14
User opened query 'PV Query: Please provide pathology, laboratory and imaging reports.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:11:50
User opened query 'PV Query: Please provide clinical consultant reports.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:11:38
Query 'PV Query: Please provide hospital records (death summary and death certificate) for October 1 admission with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:08:21

US3432295
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital records (death summary and death certificate) for October 1 admission with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:08:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User closed query 'PV Query: Please clarify if the subject had any additional symptoms (i.e. dyspnea, wheezing, hypotension, stridor, upper airway edema, other).' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:33:37
User closed query 'PV Query: Has the subject recently used OTC, herbal medications, alcohol, illicit drugs?' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:33:32
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:33:21
User closed query 'PV Query: Please provide any additional treatment given during hospitalization. Please add concomitant medications to CM eCRF. If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:33:09
User closed query 'PV Query: Please clarify if triamcinolone acetonide cream and ciclopirox cream were started on 15 Sep 2020, as narrative states that no treatment was provided.' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:33:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Oct 2020 12:32:57

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Folder: Adverse Events

Form: Adverse Events (1)

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Narrative

Audit	User	Time (GMT)
User entered '17SEP2020: PPT DEVELOPED BLISTERS ON HIS FEET ON 12SEP2020 THAT SPREAD UP HIS LEGS OVER THE FOLLOWING DAYS. HE HAD A VIRTUAL VISIT WITH HIS PCP AND THEN A DERMATOLOGIST ON 15SEP2020, TODAY THE BLISTERS HAVE SPREAD TO INVOLVE MORE OF HIS BODY. HE SPOKE TO HIS PCP AND WILL SEEK ADDITIONAL EVALUATION. 21SEP2020 UPDATE: PARTICIPANT WAS ADMITTED TO BIDMC HOSPITAL ON 17SEP2020 AFTER WE LAST SPOKE. HE REMAINS HOSPITALIZED DUE TO GENERALIZED BLISTERING RASH. COVID-19 PCR NEGATIVE AT HOSPITAL. NO SPECIFIC DIAGNOSIS FOR RASH. POSSIBLE HYPERSENSITIVITY REACTION. NO OTHER SYMPTOMS. NOW IMPROVING. ANTICIPATED DISCHARGE TO HOME SOON. 02OCT20: NO ILLICIT DRUGS, OTC OR HERBAL MEDICATIONS. DRINKS 7-8 DRINKS/WEEK. ADDITIONAL SYMPTOMS: WORSENING NIGHT SWEATS AND FATIGUE. TREATMENTS PRESCRIBED 15SEP2020- TRIAMCINOLONE ACETONIDE CREAM AND CICLOPIROX CREAM. NEW MEDICATION IN HOSPITAL- TP CLOBETASOL PROPIONATE 0.05% 1 APPLICATION. NEW DISCHARGE MEDICATION- ALLOPURINOL 200 MG PO DAILY. Notable lab results: 17SEP2020 WBC 25.7, atypical 1%, PLT 176, BUN 53, Creatine 2.2, Potassium 5.4, LDH 381 24SEP2020 WBC 27.7, HGB 10.0, HCT 31.4, Glucose, 125, UreaN 35, PLT Ct 155, Cl 109, HCO3 21, Albumin 3, Calcium 8.2, Uric Acid 7.6 Axillary Biopsy- B cell lymphoproliferative disorder, Ultrasound neck- soft tissue thickening in left tonsillar fossa, MRI neck-conglomerate R axillary & supraclavicular lymphadenopathy, Note from skin exam: diffuse paupular/vesicular/bullae rash with open blisters and yellowish serous drainage' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:13:33

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
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.' answered with 'see narrative' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:07:22
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sending via email' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:43:23
User entered '17SEP2020: PPT DEVELOPED BLISTERS ON HIS FEET ON 12SEP2020 THAT SPREAD UP HIS LEGS OVER THE FOLLOWING DAYS. HE HAD A VIRTUAL VISIT WITH HIS PCP AND THEN A DERMATOLOGIST ON 15SEP2020, TODAY THE BLISTERS HAVE SPREAD TO INVOLVE MORE OF HIS BODY. HE SPOKE TO HIS PCP AND WILL SEEK ADDITIONAL EVALUATION. 21SEP2020 UPDATE: PARTICIPANT WAS ADMITTED TO BIDMC HOSPITAL ON 17SEP2020 AFTER WE LAST SPOKE. HE REMAINS HOSPITALIZED DUE TO GENERALIZED BLISTERING RASH. COVID-19 PCR NEGATIVE AT HOSPITAL. NO SPECIFIC DIAGNOSIS FOR RASH. POSSIBLE HYPERSENSITIVITY REACTION. NO OTHER SYMPTOMS. NOW IMPROVING. ANTICIPATED DISCHARGE TO HOME SOON. 02OCT20: NO ILLICIT DRUGS, OTC OR HERBAL MEDICATIONS. DRINKS 7-8 DRINKS/WEEK. ADDITIONAL SYMPTOMS: WORSENING NIGHT SWEATS AND FATIGUE. TREATMENTS PRESCRIBED 15SEP2020- TRIAMCINOLONE ACETONIDE CREAM AND CICLOPIROX CREAM. New medication in hospital- TP Clobetasol propionate 0.05% 1 application. New discharge medication- Allopurinol 200 mg PO daily' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:16:53

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Folder: Adverse Events
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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any additional treatment given during hospitalization. Please add concomitant medications to CM eCRF. If no additional treatment was provided, please state so.' answered with 'adding to con medications and narrative.' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:15:27
Query 'PV Query: Please clarify if triamcinolone acetonide cream and ciclopirox cream were started on 15 Sep 2020, as narrative states that no treatment was provided.' answered with 'updated to reflect treatment' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:03:13
User entered '17SEP2020: PPT DEVELOPED BLISTERS ON HIS FEET ON 12SEP2020 THAT SPREAD UP HIS LEGS OVER THE FOLLOWING DAYS. HE HAD A VIRTUAL VISIT WITH HIS PCP AND THEN A DERMATOLOGIST ON 15SEP2020, TODAY THE BLISTERS HAVE SPREAD TO INVOLVE MORE OF HIS BODY. HE SPOKE TO HIS PCP AND WILL SEEK ADDITIONAL EVALUATION. 21SEP2020 UPDATE: PARTICIPANT WAS ADMITTED TO BIDMC HOSPITAL ON 17SEP2020 AFTER WE LAST SPOKE. HE REMAINS HOSPITALIZED DUE TO GENERALIZED BLISTERING RASH. COVID-19 PCR NEGATIVE AT HOSPITAL. NO SPECIFIC DIAGNOSIS FOR RASH. POSSIBLE HYPERSENSITIVITY REACTION. NO OTHER SYMPTOMS. NOW IMPROVING. ANTICIPATED DISCHARGE TO HOME SOON. 02OCT20: no illicit drugs, OTC or herbal medications. Drinks 7-8 drinks/week. Additional symptoms: worsening night sweats and fatigue. Treatments prescribed 15SEP2020- triamcinolone acetonide cream and ciclopirox cream.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:03:04
Query 'PV Query: Please clarify if the subject had any additional symptoms (i.e. dyspnea, wheezing, hypotension, stridor, upper airway edema, other).' answered with 'other notable symptoms were worsening night sweats and fatigue, ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:56:21

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Has the subject recently used OTC, herbal medications, alcohol, illicit drugs?' answered with 'No OTC, herbal medications or illicit drugs. Reports 7-8 drinks a week' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:32:06
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:35:49
User opened query 'PV Query: Has the subject recently used OTC, herbal medications, alcohol, illicit drugs?' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:35:28
User opened query 'PV Query: Please clarify if the subject had any additional symptoms (i.e. dyspnea, wheezing, hypotension, stridor, upper airway edema, other).' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:35:13
User opened query 'PV Query: Please provide any additional treatment given during hospitalization. Please add concomitant medications to CM eCRF. If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:34:57
User opened query 'PV Query: Please clarify if triamcinolone acetonide cream and ciclopirox cream were started on 15 Sep 2020, as narrative states that no treatment was provided.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 19:34:23
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).	(b) (4), (b) (6)	30 Sep 2020 19:32:59

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
User entered '17SEP2020: Ppt developed blisters on his feet on 12SEP2020 that spread up his legs over the following days. He had a virtual visit with his PCP and then a Dermatologist on 15SEP2020, no treatments prescribed. Today the blisters have spread to involve more of his body. He spoke to his PCP and will seek additional evaluation. 21SEP2020 Update: participant was admitted to BIDMC hospital on 17SEP2020 after we last spoke. He remains hospitalized due to generalized blistering rash. COVID-19 PCR negative at hospital. No specific diagnosis for rash. Possible hypersensitivity reaction. No other symptoms. Now improving. Anticipated discharge to home soon.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	21 Sep 2020 23:10:56
User entered empty.	Monica Feeley (b) (4) (b) (4)	17 Sep 2020 22:16:29

US3432295

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	21 Sep 2020 23:10:56
User entered '0'	System	17 Sep 2020 22:16:29

Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	17 Sep 2020 22:16:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:11

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '0'	System	21 Sep 2020 23:10:56

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:13
User entered 'USA-US078-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	04 Oct 2020 12:34:07

US3432295
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Inflammations, PT: Systemic inflammatory response syndrome, LLT: Systemic inflammatory response syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:45:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:45:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:05
User closed query 'PV Query: Please provide a unifying diagnosis, if applicable, for the events Diffuse bullous rash, Recurrent rash, fever, diarrhea, cardia arrest and chronic kidney disease stage III as a serious adverse event.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:36:11
Data point term sent to Coder	System	31 Oct 2020 13:28:38
User closed query 'For coding purposes, please split RECURRENT RASH, FEVER, DIARRHEA, CARDIA ARREST into sepaarate entries or provide ONE diagnosis.' (Site from System).	System	31 Oct 2020 13:28:19
Query 'For coding purposes, please split RECURRENT RASH, FEVER, DIARRHEA, CARDIA ARREST into sepaarate entries or provide ONE diagnosis.' answered with 'updated- Severe systemic inflammatory syndrome in the setting of CLL' (Site from System).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:28:19
Query 'PV Query: Please provide a unifying diagnosis, if applicable, for the events Diffuse bullous rash, Recurrent rash, fever, diarrhea, cardia arrest and chronic kidney disease stage III as a serious adverse event.' answered with 'updated- Severe systemic inflammatory syndrome in the setting of CLL' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:28:14
User entered 'Severe systemic inflammatory syndrome in the setting of CLL' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:28:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Adverse event

Audit	User	Time (GMT)
Data point term sent to Coder	System	31 Oct 2020 13:24:37
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:24:18
User entered 'RECURRENT RASH, FEVER, DIARRHEA, CARDIAC ARREST' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:24:18
User closed query 'Please complete the End of study- End of study/ study discontinuation page since subject's is discontinued' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:44:28
Query 'Please complete the End of study- End of study/ study discontinuation page since subject's is discontinued' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:00
User opened query 'Please complete the End of study- End of study/ study discontinuation page since subject's is discontinued' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 21:49:46
User opened query 'For coding purposes, please split RECURRENT RASH, FEVER, DIARRHEA, CARDIA ARREST into sepaarate entries or provide ONE diagnosis.' (Site from System).	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:50:26
Data point term sent to Coder	System	14 Oct 2020 16:31:30
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms' (Site from System).	System	14 Oct 2020 16:30:51
Query 'Per CDM Coding: Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms' answered with 'all one AE' (Site from System).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:30:51
User opened query 'PV Query: Please provide a unifying diagnosis, if applicable, for the events Diffuse bullous rash, Recurrent rash, fever, diarrhea, cardia arrest and chronic kidney disease stage III as a serious adverse event.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:06:52
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 08:53:21
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
Data point term sent to Coder	System	02 Oct 2020 20:19:05

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Folder: Adverse Events

Form: Adverse Events (2)

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Adverse event

Audit	User	Time (GMT)
User entered 'Recurrent rash, fever, diarrhea, cardia arrest'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
Query 'per source AE page the start date is 30Sep20, please check and edit' canceled (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 17:29:28
User opened query 'per source AE page the start date is 30Sep20, please check and edit' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 17:28:17
User closed query 'Per CDM: Please confirm the day part of the date and amend as the Date is required in DD MMM YYYY format.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:45:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:37:34
Query 'Per CDM: Please confirm the day part of the date and amend as the Date is required in DD MMM YYYY format.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:44
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:20
User entered '01 Oct 2020' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:20
User opened query 'Per CDM: Please confirm the day part of the date and amend as the Date is required in DD MMM YYYY format.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:13:00
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '1 Oct 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'No (N)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '02 Oct 2020' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	02 Oct 2020 20:18:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '1' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
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 Oct 2020 07:11:45
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
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 'these are filled in' (Site from System).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:58
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	02 Oct 2020 20:18:43
User entered '1'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per CDM: Please confirm the day part of the date and amend as the Date is required in DD MMM YYYY format.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:45:44
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:37:39
Query 'Per CDM: Please confirm the day part of the date and amend as the Date is required in DD MMM YYYY format.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:55
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:39
User entered '01 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:26:39
User opened query 'Per CDM: Please confirm the day part of the date and amend as the Date is required in DD MMM YYYY format.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:38:48
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '1 Oct 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per CDM: Your response to the query on "Number of Days in ICU" data point is "still in icu will update when discharged". Please review the information and also update the data and respond to this query once the subject is discharged or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:46:07
Query 'Per CDM: Your response to the query on "Number of Days in ICU" data point is "still in icu will update when discharged". Please review the information and also update the data and respond to this query once the subject is discharged or clarify. Thank you.' answered with 'this is updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:27:15
User opened query 'Per CDM: Your response to the query on "Number of Days in ICU" data point is "still in icu will update when discharged". Please review the information and also update the data and respond to this query once the subject is discharged or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:03:17
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '02 Oct 2020' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per CDM: Per response your "still in icu will update when discharged", however the subject's Hospital discharge date is updated. Please review the information and also update the data and respond to this query once the subject is out of ICU.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:46:14
Query 'Per CDM: Per response your "still in icu will update when discharged", however the subject's Hospital discharge date is updated. Please review the information and also update the data and respond to this query once the subject is out of ICU.' answered with 'this is updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	21 Oct 2020 14:27:09
User opened query 'Per CDM: Per response your "still in icu will update when discharged", however the subject's Hospital discharge date is updated. Please review the information and also update the data and respond to this query once the subject is out of ICU.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:53:42
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 06:39:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '2' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'still in icu will update when discharged' (Site from System).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:19:12
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	02 Oct 2020 20:18:43
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

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Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per CDM: Death is recorded but Action Taken is not recorded as IP Withdrawn. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:25:43
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)	26 Jan 2021 15:25:41
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 'it is because of an SAE' (Site from System).	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:23:21
Query 'Per CDM: Death is recorded but Action Taken is not recorded as IP Withdrawn. Please review and reconcile. ' answered with 'udpated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:22:49
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	25 Jan 2021 18:21:37
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:21:37
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:21:37
User opened query 'Per CDM: Death is recorded but Action Taken is not recorded as IP Withdrawn. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:28:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Dose Delayed (DOSE DELAYED)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 19:31:43
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 19:31:43
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

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Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:21:37
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 19:31:48
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 19:31:43
User entered '0' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 19:31:43
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 10:34:56
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '1'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
Query 'Per CDM: Per CCG Guidelines, Page 52, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please review and update appropriately.' canceled (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 07:19:24
User opened query 'Per CDM: Per CCG Guidelines, Page 52, Only the AE that caused the death should have outcome of 'FATAL'. All other AEs that were present at the time of death should be reported as 'Not Recovered' and end date should be blank. Please review and update appropriately.' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 07:18:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered 'Fatal (FATAL)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 17:30:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User closed query 'Per DM CLR: Narrative = PURPURA FULMINANS, COVERED ALMOST ALL BODY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:36:38
User closed query 'Per DM CLR: Narrative = ACUTE RESPIRATORY FAILURE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:36:36
User closed query 'Per DM CLR: Narrative = SUFFERED CARDIAC ARREST. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:36:34
Query 'Per DM CLR: Narrative = PURPURA FULMINANS, COVERED ALMOST ALL BODY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'this is not a separate AE. This is a symptom of the disorder' (Site from DM).	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:40:43
Query 'Per DM CLR: Narrative = ACUTE RESPIRATORY FAILURE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'This is not a separate AE. this is symptom of this disorder' (Site from DM).	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:40:12
Query 'Per DM CLR: Narrative = SUFFERED CARDIAC ARREST. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'this should not be captured as a separate AE. This is a symptom of this event, this is the same thing' (Site from DM).	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 22:39:51

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = PURPURA FULMINANS, COVERED ALMOST ALL BODY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:25:45
User opened query 'Per DM CLR: Narrative = ACUTE RESPIRATORY FAILURE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:25:39
User opened query 'Per DM CLR: Narrative = SUFFERED CARDIAC ARREST. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:25:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'PV Query: Please provide postmortem blood and lung culture results, once available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:36:28
User closed query 'PV Query: Please provide clinical consultant reports.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:36:26
User closed query 'PV Query: Please provide pathology, laboratory and imaging reports.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:36:23
User closed query 'PV Query: Please describe all medically relevant therapeutic interventions (treatment medications or procedures performed).' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:36:20
Query 'PV Query: Please provide postmortem blood and lung culture results, once available.' answered with 'sent to safety email' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:44:38
Query 'PV Query: Please provide clinical consultant reports.' answered with 'sent to safety email' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:44:36
Query 'PV Query: Please provide pathology, laboratory and imaging reports.' answered with 'sent to safety email' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:44:34

US3432295
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please describe all medically relevant therapeutic interventions (treatment medications or procedures performed).' answered with 'updated to con meds' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	31 Oct 2020 13:44:27
User closed query 'PV Query: Was subject tested for COVID-19 during second hospitalization on October 1? If so, please provide test results and lab report.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:16:11
Query 'PV Query: Please provide hospital records (death summary and death certificate) for October 1 admission with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' canceled (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:31:22
User opened query 'PV Query: Please provide postmortem blood and lung culture results, once available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:20:08
Query 'PV Query: Was subject tested for COVID-19 during second hospitalization on October 1? If so, please provide test results and lab report.' answered with 'Participant tested 01OCT2020 with nasal swab for COVID-19- negative' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	29 Oct 2020 13:43:39
User closed query 'PV Query: Please provide autopsy report, if an autopsy was performed.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 14:57:43
Query 'PV Query: Please provide autopsy report, if an autopsy was performed.' answered with 'preliminary autopsy report provided' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	23 Oct 2020 22:00:59
User closed query 'PV Query: Please consider adding acute kidney injury on chronic kidney disease stage III as a serious adverse event.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:44:16
Query 'PV Query: Please consider adding acute kidney injury on chronic kidney disease stage III as a serious adverse event.' answered with 'CKD stage three is a pre-existing medical history. Not an SAE' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:35:57
User opened query 'PV Query: Please provide clinical consultant reports.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:11:15
User opened query 'PV Query: Was subject tested for COVID-19 during second hospitalization on October 1? If so, please provide test results and lab report.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:10:25

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide pathology, laboratory and imaging reports.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:10:05
User opened query 'PV Query: Please describe all medically relevant therapeutic interventions (treatment medications or procedures performed).' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:09:36
User opened query 'PV Query: Please provide autopsy report, if an autopsy was performed.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:09:03
User opened query 'PV Query: Please provide hospital records (death summary and death certificate) for October 1 admission with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:08:37
User opened query 'PV Query: Please consider adding acute kidney injury on chronic kidney disease stage III as a serious adverse event.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:06:22
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:53:18

US3432295
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
User entered '02OCT20:PT HAD BEEN DOING WELL AT HOME SINCE DISCHARGE FROM HOSPITAL 24SEP2020 FOR DIFFUSE BULLOUS RASH. ON 01OCT2020, HE REPORTEDLY DEVELOPED WORSENING OF RASH, FEVER, AND DIARRHEA, PRESENTED TO BIDMC HOSPITAL AND WAS ADMITTED. DOING POORLY THERE, SUFFERED CARDIAC ARREST. RECOVERED WITH RESUSCITATION, REMAINS IN ICU THERE. SPOKE WITH ICU MEDICAL TEAM AND PATIENTS WIFE FOR THIS INFORMATION, ALSO SUBMITTING MEDICAL RECORDS. ONCOLOGY TEAM THERE EVALUATING TO DETERMINE WHETHER CURRENT EVENT MAY BE DUE TO TRANSFORMATION OF HIS UNDERLYING CLL. 03OCT2020: Update from Death Note- participant admitted with acute SOB Had recent hospitalization for rash. Found to have acute respiratory failure. PEA arrest 02OCT2020. Purpura fulminans, covered almost all body. Participant designated CMO. Time of death 16:45 on 02OCT2020.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	03 Oct 2020 18:10:12
User entered '02OCT20:Pt had been doing well at home since discharge from hospital 24SEP2020 for diffuse bullous rash. On 01OCT2020, he reportedly developed worsening of rash, fever, and diarrhea, presented to BIDMC hospital and was admitted. Doing poorly there, suffered cardiac arrest. Recovered with resuscitation, remains in ICU there. Spoke with ICU medical team and patients wife for this information, also submitting medical records. Oncology team there evaluating to determine whether current event may be due to transformation of his underlying CLL.'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	02 Oct 2020 20:18:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	02 Oct 2020 20:18:43

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:11

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	02 Oct 2020 20:18:43

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 18:24:41
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 18:22:44

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:21:43
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' answered with 'unable to obtain information as participant passed away' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 19:32:19
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:06:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Supraclavicular lymph nodes enlarged - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:30:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:30:03
Data point term sent to Coder	System	20 Nov 2020 15:25:56
User entered 'Supraclavicular lymphadenopathy'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

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Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '22 Sep 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

Folder: Adverse Events

Form: Adverse Events (3)

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AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User entered empty.	System	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '02 Oct 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User entered empty.	System	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

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Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'None (NONE)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '1'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:37:11
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 15:25:47

US3432295

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User entered '0'	System	20 Nov 2020 15:25:47

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26
User entered '1'	System	20 Nov 2020 15:25:47

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:11

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:30:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:38:01
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:35:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:37:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:37:55
Data point term sent to Coder	System	26 Aug 2020 14:36:44
User entered 'levothyroxine'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'hypothyroidism'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '50'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'ug (ug)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'UN UNK 2005'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '804 (804)'	System	26 Aug 2020 14:36:32

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:38:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:38:42
Data point term sent to Coder	System	26 Aug 2020 14:37:46
User entered 'tamsulosin'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Benign prostatic hyperplasia'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0.4'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'UN UNK 2017'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '804 (804)'	System	26 Aug 2020 14:37:13

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:10:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:10:47
Data point term sent to Coder	System	26 Aug 2020 14:37:46
User entered 'fluticasone'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

FDA-CBER-2022-1614-2605369

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'idiopathic rhinitis'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '50'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'ug (ug)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Nasal (NASAL)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'UN UNK 2000'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	26 Aug 2020 14:37:45

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '1'	System	26 Aug 2020 14:37:45

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '804 (804)'	System	26 Aug 2020 14:37:45

FDA-CBER-2022-1614-2605386

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:59:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:59:45
Data point term sent to Coder	System	10 Nov 2020 22:11:10
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:10:33
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 10:30:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 10:30:01
Data point term sent to Coder	System	16 Sep 2020 15:27:57
User entered 'Triamcinolone acetonide cream'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the RASH (e.g. (Urticarial vs Non-urticarial; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:03:30
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
Query 'Per DM CLR: Please update the indication and clarify the type and location of the RASH (e.g. (Urticarial vs Non-urticarial; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:10:37
User entered 'DIFFUSE BULLOUS RASH (NON-URTICARIAL)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:10:33
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the RASH (e.g. (Urticarial vs Non-urticarial; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:41:20
User entered 'Rash'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '1'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Other (OTHER)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'application'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'as needed (PRN)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Topical (TOPICAL)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '15 Sep 2020'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered empty.	System	16 Sep 2020 15:27:22

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: CICLOPIROX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:31:44
Data point term sent to Coder	System	10 Nov 2020 22:11:10
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:10:45
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: CICLOPIROX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:54:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:54:45
Data point term sent to Coder	System	16 Sep 2020 15:28:59
User entered 'ciclopirox cream'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the RASH (e.g. (Urticarial vs Non-urticarial; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:01:26
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
Query 'Per DM CLR: Please update the indication and clarify the type and location of the RASH (e.g. (Urticarial vs Non-urticarial; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'udpated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:10:48
User entered 'DIFFUSE BULLOUS RASH (NON-URTICARIAL)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:10:45
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the RASH (e.g. (Urticarial vs Non-urticarial; bilateral, left, right; arms, legs, face etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:42:50
User entered 'rash'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '1'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Other (OTHER)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'application'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'as needed (PRN)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Topical (TOPICAL)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '15 Sep 2020'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:52:15
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	07 Apr 2021 23:09:12
DataPoint Un-verified.	Jun Bai Park Chang (b) (4)	07 Apr 2021 23:09:08
User entered 'No (N)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	07 Apr 2021 23:09:08
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 19:52:09
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Un-verified.	Jun Bai Park Chang (b) (4)	07 Apr 2021 23:09:08
User entered '02 Oct 2020' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	07 Apr 2021 23:09:08
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Phoebe Cunningham (b) (4)	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User entered empty.	System	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User entered empty.	System	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:54
User entered empty.	System	16 Sep 2020 15:28:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 07:34:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 07:34:04
Data point term sent to Coder	System	25 Jan 2021 17:26:22
DataPoint Un-verified.	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
Coding entries removed.	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
User entered 'CLOBETASOL (0.05%)' reason for change: Per Query Resolution	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:05:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:05:49
Data point term sent to Coder	System	10 Nov 2020 22:11:10
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:11:00
User closed query 'Please confirm if this is Clobetasol.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 14:23:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:22:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:22:29
Data point term sent to Coder	System	14 Oct 2020 16:25:20
Query 'Please confirm if this is Clobetasol.' answered with 'yes. updated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:28
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:22
User entered 'CLOBETASOL' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:22
User opened query 'Please confirm if this is Clobetasol.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 19:37:59
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:15:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:15:41
Data point term sent to Coder	System	02 Oct 2020 21:20:57
User entered 'Cloberasol'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'DIFFUSE BULLOUS RASH (NON-URTICARIAL)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:11:00
User entered 'rash'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Note, 0.05% is a concentration, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:23:21
Query 'Per DM CLR: Note, 0.05% is a concentration, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Update as appropriate. ' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:19
DataPoint Un-verified.	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
User entered '1' reason for change: Data Entry Error	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
User opened query 'Per DM CLR: Note, 0.05% is a concentration, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:35:21
User closed query 'per source con-med log dose is : 0.05%, please check and edit.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 15:35:17
Query 'per source con-med log dose is : 0.05%, please check and edit.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:32:05
User entered '0.05' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:31:50
User opened query 'per source con-med log dose is : 0.05%, please check and edit.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:49:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 19:48:54
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
User entered '0.01'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Other (OTHER)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Un-verified.	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
User entered 'application' reason for change: Data Entry Error	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:26:08
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'percent'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:37:11
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Topical (TOPICAL)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '17 Sep 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '17 Sep 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User entered '1'	System	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User entered '1'	System	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:07:58
User entered '804 (804)'	System	02 Oct 2020 21:20:40

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
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 02:05:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:05:44
Data point term sent to Coder	System	10 Nov 2020 22:12:11
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:11:12
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)	03 Oct 2020 07:23:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:23:44
Data point term sent to Coder	System	02 Oct 2020 21:21:58
User entered 'Allopurinol'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

FDA-CBER-2022-1614-2605443

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:24:29
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Participant reported taking this medication for said indication.' (Site from DM).	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:27:03
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 19:53:23
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'DIFFUSE BULLOUS RASH (NON-URTICARIAL)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:11:12
User entered 'rash'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '200'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

FDA-CBER-2022-1614-2605446

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'once daily (QD)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '24 Sep 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered '0'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:54:23
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:32:31
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:32:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:35:29
User closed query 'Per source con-med log: stop date: 02Oct20, please check and edit' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 15:35:27
Query 'Per source con-med log: stop date: 02Oct20, please check and edit' answered with 'udpated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:32:37
User entered '02 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:32:31
User opened query 'Per source con-med log: stop date: 02Oct20, please check and edit' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:51:16
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 19:50:45
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User entered '1'	System	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User entered '1'	System	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:04
User entered '804 (804)'	System	02 Oct 2020 21:21:12

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:31:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:31:55
Data point term sent to Coder	System	20 Nov 2020 14:34:09
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:33:11
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:06:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:06:32
Data point term sent to Coder	System	14 Oct 2020 16:21:10
User entered 'Hydroxyzine'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:36
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PRURITUS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:44:59
Query 'Per DM CLR: Please update the indication to reflect the location and type of PRURITUS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'udpated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:33:15
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:33:11
User entered 'PRUITIS (entire body)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:33:11
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PRURITUS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:24:15
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:38
User entered 'Pruitis'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:39
User entered '25'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:42
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:43
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:45
User entered 'as needed (PRN)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:47
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:49
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:50
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:53
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:55
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:58
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:53:00
User entered '02 Oct 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:53:01
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User entered empty.	System	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User entered empty.	System	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:26
User entered empty.	System	14 Oct 2020 16:20:56

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:22:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:22:39
Data point term sent to Coder	System	14 Oct 2020 16:22:13
User entered 'Tylenol'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:03
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 07:24:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this is part of the SAE' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:33:33
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:23:45
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:05
User entered 'Fever'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:07
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:42
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:44
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:49:47
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:42
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:43
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:45
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:27:09
Query 'Please confirm if start date is 30Sep, since subject was admitted on 01Oct20, please review and update the EDC for AE start date also' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:27:08
User opened query 'Please confirm if start date is 30Sep, since subject was admitted on 01Oct20, please review and update the EDC for AE start date also' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 17:51:35
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

FDA-CBER-2022-1614-2605489

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:51:47
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:51:49
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:27:56
Query ' Please confirm if stop date is 30Sep, since subject was admitted on 01Oct20, please review and update the EDC for AE start date also' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:27:55
User opened query ' Please confirm if stop date is 30Sep, since subject was admitted on 01Oct20, please review and update the EDC for AE start date also' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 17:52:10
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:52:13
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User entered empty.	System	14 Oct 2020 16:21:26

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User entered empty.	System	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:20
User entered empty.	System	14 Oct 2020 16:21:26

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 05:50:56
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 Apr 2021 05:50:56
Data point term sent to Coder	System	09 Apr 2021 14:12:58
User closed query 'DM-Coding: for term CEFTRIAXONE/AZITHROMYCIN, Please provide the trade name for this combination medication, if not a marketed medication then please split into separate record lines, Example: 1) CEFTRIAXONE 2) AZITHROMYCIN' (Site from System).	System	09 Apr 2021 14:12:40
Query 'DM-Coding: for term CEFTRIAXONE/AZITHROMYCIN, Please provide the trade name for this combination medication, if not a marketed medication then please split into separate record lines, Example: 1) CEFTRIAXONE 2) AZITHROMYCIN' answered with 'updated to separate entries' (Site from System).	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:12:40
Data point term sent to Coder	System	09 Apr 2021 14:10:48
User entered 'CEFTRIAXONE' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:10:31
User opened query 'DM-Coding: for term CEFTRIAXONE/AZITHROMYCIN, Please provide the trade name for this combination medication, if not a marketed medication then please split into separate record lines, Example: 1) CEFTRIAXONE 2) AZITHROMYCIN' (Site from System).	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:07:28
Data point term sent to Coder	System	25 Jan 2021 17:29:26
User closed query 'CDM-Coding: Please expand/spell out the reported abbreviation CTX.' (Site from System).	System	25 Jan 2021 17:28:27

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US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Query 'CDM-Coding: Please expand/spell out the reported abbreviation CTX.' answered with 'Updated' (Site from System).	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:28:27
Data point term sent to Coder	System	25 Jan 2021 17:28:24
DataPoint Un-verified.	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:27:36
User entered 'ceftriaxone/AZITHROMYCIN' reason for change: Data Entry Error	Alexander Mills (b) (4) (b) (4)	25 Jan 2021 17:27:36
User closed query 'Per DM CLR: Please review medication name to confirm if these medication is a combination product or was given at the same time. Please confirm and update to record non-combination drug into separate loglines, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:18:30
User opened query 'CDM-Coding: Please expand/spell out the reported abbreviation CTX.' (Site from System).	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:24:03
Data point term sent to Coder	System	20 Nov 2020 14:35:09
Query 'Per DM CLR: Please review medication name to confirm if these medication is a combination product or was given at the same time. Please confirm and update to record non-combination drug into separate loglines, otherwise clarify.' answered with 'combination ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:34:14
User opened query 'Per DM CLR: Please review medication name to confirm if these medication is a combination product or was given at the same time. Please confirm and update to record non-combination drug into separate loglines, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:26:35
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:43:30
Data point term sent to Coder	System	14 Oct 2020 16:22:15
User entered 'CTX/Azithromycin'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

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US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:43:32
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:45:23
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:24:30
Query 'Per DM CLR: Please update the indication to reflect the location and type of RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:34:51
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:34:46
User entered 'RASH (DIFFUSE BULLOUS RASH NON-URTICARIAL)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:34:46
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of RASH. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:26:01
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:43:35
User entered 'Rash'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:43:51
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:43:58
User entered 'Other (OTHER)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:00
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:04
User entered 'once (ONCE)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:08
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:11
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:18
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:44:21
User entered '0'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:47:09
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:47:10
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:47:13
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User entered empty.	System	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User entered empty.	System	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:43
User entered empty.	System	14 Oct 2020 16:22:10

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:25:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:25:07
Data point term sent to Coder	System	14 Oct 2020 16:23:17
User entered 'Levothyroxine Sodium'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:22
User entered 'Hypothyroidism'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:24
User entered '75'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:25
User entered 'ug (ug)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:29
User entered 'other (OTHER)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:31
User entered '2x/week'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:33
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:13:36
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:14:24
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:14:27
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:14:29
User entered '02 Oct 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:46:06
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User entered empty.	System	14 Oct 2020 16:22:55

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User entered empty.	System	14 Oct 2020 16:22:55

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:31
User entered empty.	System	14 Oct 2020 16:22:55

FDA-CBER-2022-1614-2605533

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:07
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:42:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:42:32
Data point term sent to Coder	System	14 Oct 2020 16:24:18
User entered 'Prednisolone Acetate 1%'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:09
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:49:32
User closed query 'Please add Indication, review the hospital records for details' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:49:31
Query 'Please add Indication, review the hospital records for details' answered with 'no indication noted' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 22:05:20
User opened query 'Please add Indication, review the hospital records for details' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 17:39:55
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:32
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:11
User entered 'UNK'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:14
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:58
User entered 'Other (OTHER)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:39:59
User entered 'drop'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:01
User entered 'three times daily (TID)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:03
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 07:33:01
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'correct' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 14:35:22
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:27:13
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:04
User entered 'Intraocular (INTRAOCULAR)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:06
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:08
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:12
User entered '1'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:14
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:16
User entered '02 Oct 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:40:20
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User entered '3'	System	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User entered '1'	System	14 Oct 2020 16:24:05

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:11
User entered '804 (804)'	System	14 Oct 2020 16:24:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 17:37:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:40:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:40:25
Data point term sent to Coder	System	09 Apr 2021 14:12:57
Data point term sent to Coder	System	09 Apr 2021 14:11:54
User entered 'AZITHROMYCIN'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered 'RASH (DIFFUSE BULLOUS RASH NON-URTICARIAL)' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:59
User entered 'rash'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered 'unk'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered 'Other (OTHER)'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered 'unknown'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	09 Apr 2021 14:12:11
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	09 Apr 2021 14:12:11
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	09 Apr 2021 14:11:59
User entered 'once (ONCE)'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered empty.	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered empty.	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Apr 2021 14:11:59
User entered '30 Sep 2020' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:59
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Apr 2021 14:11:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered '0'	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 14:11:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 14:11:59
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:59
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 14:11:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Apr 2021 14:12:11
User entered '30 Sep 2020' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:12:11
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Apr 2021 14:11:59
User entered '20 Sep 2020' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:59
User entered empty.	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 14:11:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 14:11:59
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:59
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 14:11:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User entered empty.	System	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User entered empty.	System	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:37:11

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:08:48
User entered empty.	System	09 Apr 2021 14:11:09

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:37:11

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:24:29
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:40:43

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:17:46
User entered '4 Sep 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	02 Oct 2020 22:05:56
User entered '2 Sep 2020'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:14

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:17:48
User entered 'Axillary Biopsy' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:05:56
User entered 'Cataract Surgery'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:14

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:17:51
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. MedHistory) as there is a recorded conditions in the MedHistory eCRF that possibly matches this procedure. Reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:35:52
Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. MedHistory) as there is a recorded conditions in the MedHistory eCRF that possibly matches this procedure. Reconcile and update as appropriate, otherwise provide clarification.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:01
User entered 'Medical History (MH)' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:05:56
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. MedHistory) as there is a recorded conditions in the MedHistory eCRF that possibly matches this procedure. Reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:20:08
User entered 'Other (OTHER)'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:17:53
User entered empty; reason for change New Information	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:05:56
User entered 'Treatment'	Phoebe Cunningham (b) (4)	02 Sep 2020 17:41:14

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:03
User entered '17 Sep 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:16

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:06
User entered 'Skin biopsy'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:16

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:07
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:16

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:09
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:16

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:17
User entered '22 Sep 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:28

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:20
User entered 'MRI- neck'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:28

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:22
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:28

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:25
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:28

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:30
User entered '22 Sep 2020'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:43

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:32
User entered 'Ultrasound- neck'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:43

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:33
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:43

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:35
User entered empty.	Monica Feeley (b) (4) (b) (4)	02 Oct 2020 22:06:43

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:49
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:40
User entered '30 Sep 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:19:50

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:18:59
User entered 'CT scan (chest, abdomen, pelvis)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:19:50

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:19:01
User entered 'Medical History (MH)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:19:50

US3432295
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 17:37:11
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:19:04
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:19:50

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:21:34
User entered '17 Sep 2020'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:02

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:21:37
User entered 'EKG'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:02

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:21:40
User entered 'Medical History (MH)'	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:02

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:37:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:21:42
User entered empty.	Monica Feeley (b) (4) (b) (4)	14 Oct 2020 16:20:02

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:11
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	22 Oct 2020 21:20:51

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:37:11

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:11
User entered 'cataract surgery'	Julia Klopfer (b) (4) (b) (4)	22 Oct 2020 21:20:51

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:37:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:11
User entered 'Medical History (MH)'	Julia Klopfer (b) (4) (b) (4)	22 Oct 2020 21:20:51

US3432295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:37:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:11
User entered empty.	Julia Klopfer (b) (4) (b) (4)	22 Oct 2020 21:20:51

US3432295
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 17:37:11
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:37
User entered '2 Oct 2020'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:12

US3432295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:37:11

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:37
User entered 'Death (DEATH)'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:12

US3432295

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:37
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:12

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
User entered '2 Oct 2020'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:11

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
User entered 'Death (DEATH)'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	21 Jan 2021 16:51:53
User entered empty; reason for change Per Query Resolution	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:51:53
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	21 Jan 2021 16:51:35
DataPoint Un-verified.	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:51:35
User entered 'AE #1, AE #2' reason for change: Per Query Resolution	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:51:35
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:37:11

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User closed query 'Per CDM RQ: Response noted. Please add AE record numbers to data field. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 17:19:32
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	21 Jan 2021 16:52:45
Query 'Per CDM RQ: Response noted. Please add AE record numbers to data field. ' answered with 'please clarify which data field. Adding to either specify field creates additional queries that cannot be resolved with replies.' (Site from DM).	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:52:39
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	21 Jan 2021 16:51:53
User opened query 'Per CDM RQ: Response noted. Please add AE record numbers to data field. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:27:05
User closed query 'Per CDM: please consider adding record number (i.e. Adverse Event #1, etc. or AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:27:05
Query 'Per CDM: please consider adding record number (i.e. Adverse Event #1, etc. or AE#1, etc.)' answered with 'AE #1 and AE #2. Please see death listed on these AEs.' (Site from DM).	Jessica Cauley (b) (4) (b) (4)	14 Jan 2021 22:03:26
User opened query 'Per CDM: please consider adding record number (i.e. Adverse Event #1, etc. or AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:17:05
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
Query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify ' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:38:53
User opened query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:48:54

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:11

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered 'Adverse event (ADVERSE EVENT)'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:11

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered empty; reason for change Per Query Resolution	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:52:45
DataPoint Un-verified.	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:51:53
User entered 'Ae # 1, AE # 2' reason for change: Data Entry Error	Jessica Cauley (b) (4) (b) (4)	21 Jan 2021 16:51:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:11

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
User entered '2 Oct 2020'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:37:11
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:00:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:23:42
User entered 'Unknown (UNK)'	Monica Feeley (b) (4) (b) (4)	20 Oct 2020 15:44:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

FDA-CBER-2022-1614-2605623

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605638

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '22/Sep/2020 10:27'	System	22 Sep 2020 14:27:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 14:27:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605653

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

FDA-CBER-2022-1614-2605654

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

FDA-CBER-2022-1614-2605658

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '02/Oct/2020 08:02'	System	02 Oct 2020 12:02:58

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:02:58

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605671

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605674

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:37:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '04/Oct/2020 08:34'	System	04 Oct 2020 12:34:52

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:37:40
User entered '1'	(b) (4), (b) (6)	04 Oct 2020 12:34:52

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

FDA-CBER-2022-1614-2605695

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:37:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '05/Oct/2020 14:39'	System	05 Oct 2020 14:39:26

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:44:40
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 14:39:26

FDA-CBER-2022-1614-2605697

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605703

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:37:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '15/Oct/2020 09:44'	System	15 Oct 2020 13:44:48

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:41:51
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 13:44:48

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '22/Oct/2020 15:42'	System	22 Oct 2020 15:42:08

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 14:58:04
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 15:42:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605741

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:37:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:37:03
User entered '26/Oct/2020 14:58'	System	26 Oct 2020 14:58:15

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)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:36:55
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:37:03
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 14:58:15

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:20:13
User entered '02/Nov/2020 14:37'	System	02 Nov 2020 14:37:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 17:37:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:46:54
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:20:13
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 14:37:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605779

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

FDA-CBER-2022-1614-2605781

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (9)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '26/Jan/2021 12:47'	System	26 Jan 2021 17:47:33

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:47:45
User entered '1'	(b) (4), (b) (6)	26 Jan 2021 17:47:33

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

FDA-CBER-2022-1614-2605799

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605800

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (10)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '11/Feb/2021 13:01'	System	11 Feb 2021 18:01:50

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 10:31:36
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '1'	(b) (4), (b) (6)	11 Feb 2021 18:01:50

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605814

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605818

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:37:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered '08/Apr/2021 09:07'	System	08 Apr 2021 16:07:09

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:37:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 10:31:36
User entered '1'	(b) (4), (b) (6)	08 Apr 2021 16:07:09

Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'USA-US078-2020-MRNA-1273-P301000002'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 12:34:34
Un-reviewed for Safety.	System	03 Oct 2020 17:30:54
User entered 'Yes (Y)'	System	03 Oct 2020 17:30:54
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605826

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:27:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605829

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'No (N)'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Lindsey'	System	22 Sep 2020 14:27:14

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'Baden'	System	22 Sep 2020 14:27:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:27:35
User entered 'MA'	System	22 Sep 2020 14:27:14

FDA-CBER-2022-1614-2605836

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 17:37:11

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:04:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:02:50
User entered 'US'	System	22 Sep 2020 14:27:41

US3432295

Folder: SAE USA-US078-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:11

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User entered '12'	System	13 Apr 2021 10:31:51
User entered '11'	System	08 Apr 2021 16:07:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:21:12
User entered '10'	System	11 Feb 2021 18:01:50
User entered '9'	System	26 Jan 2021 17:47:33
User entered '8'	System	02 Nov 2020 14:37:08
User entered '7'	System	26 Oct 2020 14:58:15
User entered '6'	System	22 Oct 2020 15:42:08
User entered '5'	System	15 Oct 2020 13:44:48
User entered '4'	System	05 Oct 2020 14:39:26
User entered '3'	System	04 Oct 2020 12:34:52
User entered '2'	System	02 Oct 2020 12:02:58
User entered '1'	System	22 Sep 2020 14:27:41

FDA-CBER-2022-1614-2605839

US3432295
Folder: SAE USA-US078-2020-MRNA-1273-P301000002
Form: Safety Report Form (12)
Generated On: 09 Jun 2021 17:37:11
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered '13/Apr/2021 10:31'	System	13 Apr 2021 10:31:51

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:43:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:12:10
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 10:31:51

FDA-CBER-2022-1614-2605841