

US3632032 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:13:08

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US3632032

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

[Participant ID](#)

US3632032

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

US3632032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 SEP 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) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 13:36:38

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Date of Informed Consent (<i>dd MMM yyyy</i>)	1 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 13:36:38

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 13:36:38

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 13:36:38

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JAN 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	01 JAN 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	GALLBLADDER REMOVED
Start date (dd MMM yyyy)	01 JAN 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 JAN 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	SLEEVE GASTRECTOMY
Start date (dd MMM yyyy)	01 OCT 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 OCT 2013
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2013
Start Year (derived)	2013
Stop Month and Year (derived)	OCT 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	CARDIAC ABLATION
Start date (dd MMM yyyy)	01 OCT 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 APR 2013
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2012
Start Year (derived)	2012
Stop Month and Year (derived)	APR 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	RIGHT OVARY AND TUBE REMOVED
Start date (dd MMM yyyy)	01 APR 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 APR 1993
Stop date completely unknown	False
Start Month and Year (derived)	APR 1993
Start Year (derived)	1993
Stop Month and Year (derived)	APR 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	RIGHT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	01 JUN 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 OCT 1997
Stop date completely unknown	False
Start Month and Year (derived)	JUN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	OCT 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	ANEMIA (LOW-GRADE) (TWO LOW TO BE TREATABLE)
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	MILD ASTHMA (ON INHALER AS NEEDED RARELY NEEDED)
Start date (dd MMM yyyy)	01 JAN 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)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	ALLERGIES (POLLEN/HAY FEVER)
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 (11)

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	SEVERE OBESITY
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) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Condition	MENOPAUSE
Start date (dd MMM yyyy)	01 JAN 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)	_____

US3632032

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:24
Height (xxx.x)	163 cm
Weight (xxx.x)	308 lb
BMI (xxx.x)	52.69299 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	188 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 13:36:38

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 13:36:38

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Date of assessment (dd MMM yyyy) 01 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) 01 JAN 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 13:36:38

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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

GOES TO THE GROCERY STORE,
NAIL SALON, VOLUNTEERS AT
POLLING PLACE AND GOES TO
THE MOVIES ONCE A MONTH

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 13:36:38

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 13:37:27

Generated On: 10 Jun 2021 09:13:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 SEP 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) 22 Feb 2021 13:37:26

Generated On: 10 Jun 2021 09:13:08

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 146180

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) 22 Feb 2021 13:37:27

Generated On: 10 Jun 2021 09:13:08

Height	63.5 in
Weight	308 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 13:37:27

Generated On: 10 Jun 2021 09:13:08

Height	63.5 in
Weight	308 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:22
Temperature (xxx.x)	96.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 13:37:27

Generated On: 10 Jun 2021 09:13:08

Height	63.5 in
Weight	308 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:15
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	182 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	107 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 13:37:26

Generated On: 10 Jun 2021 09:13:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 13:37:26

Generated On: 10 Jun 2021 09:13:08

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 13:42 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 13:42

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 13:37:26

Generated On: 10 Jun 2021 09:13:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

12:58 (24 HR)

Collection date and time (derived)

16 SEP 2020 12:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:02	16 SEP 2020 13:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 13:36:39

Generated On: 10 Jun 2021 09:13:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 14:20

PC Open Date & Time

16 SEP 2020 14:02

PC Close Date & Time

16 SEP 2020 16:32

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	16 SEP 2020 21:15
PC Open Date & Time	16 SEP 2020 17:27
PC Close Date & Time	17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 20:57

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 20:57

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:28

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

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

21 SEP 2020 21:14

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

22 SEP 2020 21:29

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 14:22

PC Open Date & Time

16 SEP 2020 14:02

PC Close Date & Time

16 SEP 2020 16:32

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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

16 SEP 2020 21:16

PC Open Date & Time

16 SEP 2020 17:27

PC Close Date & Time

17 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:58

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 20:18

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:29

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:14

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 21:30

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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 ☐

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:23
PC Open Date & Time	16 SEP 2020 14:02
PC Close Date & Time	16 SEP 2020 16:32

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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 ☐

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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

No ☐

Yes ☒

PC Time stamp	16 SEP 2020 21:22
PC Open Date & Time	16 SEP 2020 17:27
PC Close Date & Time	17 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

Yes ☐	
PC Time stamp	17 SEP 2020 20:58
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1027

EAB) (1725)

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

Yes ☐	
PC Time stamp	18 SEP 2020 20:58
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 1027

EAB) (1725)

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

Yes ☐	
PC Time stamp	19 SEP 2020 20:19
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

Yes ☐	
PC Time stamp	20 SEP 2020 20:30
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

Yes ☐	
PC Time stamp	21 SEP 2020 21:15
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

Yes ☐	
PC Time stamp	22 SEP 2020 21:30
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3632032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 13:36:38

Generated On: 10 Jun 2021 09:13:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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 _____

US3632032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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	

US3632032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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	

US3632032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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.

US3632032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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?

US3632032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

Was the sample collected? Yes ☐
No ☐

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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			
Nasopharyngeal Swab 2			

US3632032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3632032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:13:08

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

US3632032

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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 ☐

US3632032

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3632032

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

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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 _____

US3632032

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

Form: Unblinding

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

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

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

Was the participant unblinded? Yes ☐
No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐
Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*) _____

Participant randomization assignment mRNA-1273 ☐
Placebo ☐

Actual Dose 1 mRNA-1273 ☐
Placebo ☐
Not Administered ☐

Actual Dose 2 mRNA-1273 ☐
Placebo ☐
Not Administered ☐

Will participant receive mRNA-1273? Yes ☐
No ☐

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3632032

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

Was the sample collected? Yes ☐
No ☐

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3632032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

Was the sample collected? Yes ☐
No ☐

Collection date (dd MMM yyyy) _____

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

Collection Date and Time (derived) _____

US3632032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

AEID	USA-US120-2020-MRNA-1273-P30 1000001
Adverse event	HYPERTENSIVE EMERGENCY
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)	16 SEP 2020
Start time (00:00-23:59)	14:15 (24 HR)
AE start date and time (derived)	16 SEP 2020 14:15
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	16:27 (24 HR)
AE End Date and Time (derived)	18 SEP 2020 16:27
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	True
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 ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

ASKED BY STUDY STAFF TO
EVALUATE PATIENT FOR
EXTREMELY HIGH BP 30MIN
POST-VACCINE. PRE-VACCINE
BP 155/84; 30 MIN POST
VACCINE BP 182/107 14:15;
179/106 AT 14:47 AND 220/113 AT
15:40. RECOMMENDED THAT
PATIENT GO TO ED. ADVISED
PATIENT OF RISKS OF END
ORGAN DAMAGE, STROKE,
VISION LOSS AND MI. PATIENT
IS AN RN AND UNDERSTOOD
ALL RISKS. CONTACTED
PATIENT'S CARDIOLOGIST
WHO STATED PATIENT WITH
MEDICAL NON-COMPLIANCE
AND ALSO RECOMMENDED
PATIENT GO TO ED.
DISCUSSED WITH PATIENT
WHO REMAINED
ASYMPTOMATIC. PATIENT
REFUSED 911 CALL AND ED
ADMISSION AND OPTED TO GO
HOME AND MANAGE HER BP
WITH ADDITIONAL
MEDICATIONS. SHE WILL BE
FOLLOWED UP PER PROTOCOL
BY STUDY TEAM. PATIENT
STATED SHE IS AN RN AND
UNDERSTANDS ALL RISKS AND
PLANS TO FOLLOW UP WITH
CARDIOLOGIST AS AN
OUTPATIENT. FOLLOWED UP
WITH PARTICIPANT ON 18 SEP
2020, BLOOD PRESSURE WAS
169/87, WHICH PARTICIPAT
VERIFIED WAS WITHIN HER
NORMS.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

AEID

Adverse event

ATRIAL FIBRILLATION,
WORSENING

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)

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 ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

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	PER-EXISTING AFIB, NOW INCREASED EPISODES IN FREQUENCY AND DURATION.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

AEID

Adverse event MIGRAINE

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) 04 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) 04 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

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

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

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

Yes ☒

No ☐

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

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 UNK 2000
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 UNK 1996	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 05 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	☒

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication FLECANIDE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication XOPENEX INHALER

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication POLLEN/HAY FEVER
ALLERGIES

Dose per administration 10

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 APR 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	☐

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 OCT 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 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	☐

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

Name of Medication IPRATROPIUM
BROMIDE/ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

Dose per administration UNKNOWN

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

If dose unit is Other, specify DOSE IS 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Feb 2021 13:36:36

Generated On: 10 Jun 2021 09:13:08

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 UNK 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3632032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Mar 2021 19:00:53

Generated On: 10 Jun 2021 09:13:08

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3632032

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

Date of dosing discontinuation (dd MMM yyyy) 19 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

PARTICIPANT REQUESTED TO WITHDRAW DUE TO HEALTH CHALLENGES AND A NEW JOB, MAKING IT DIFFICULT TO KEEP VISITS/STUDY PROCEDURES.

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 22 Feb 2021 13:36:37

Generated On: 10 Jun 2021 09:13:08

Date of study discontinuation/completion (dd MMM yyyy) 19 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

PARTICIPANT REQUESTED TO WITHDRAW DUE TO HEALTH CHALLENGES AND A NEW JOB, MAKING IT DIFFICULT TO KEEP VISITS/STUDY PROCEDURES.

If reason for discontinuation is Death, main cause of death

Adverse event	☐
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	☐
No	☐
Unknown	☐

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:39:20

Generated On: 10 Jun 2021 09:13:08

SAEID	USA-US120-2020-MRNA-1273-P301000001
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:39:20

Generated On: 10 Jun 2021 09:13:08

SAEID	USA-US120-2020-MRNA-1273-P301000001
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/SEP/2020 11:07
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

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:39:20

Generated On: 10 Jun 2021 09:13:08

SAEID	USA-US120-2020-MRNA-1273-P301000001
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 18:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:39:20

Generated On: 10 Jun 2021 09:13:08

SAEID	USA-US120-2020-MRNA-1273-P301000001
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/SEP/2020 08:20
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

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:39:20

Generated On: 10 Jun 2021 09:13:08

SAEID	USA-US120-2020-MRNA-1273-P301000001
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/OCT/2020 11:55
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

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:39:20

Generated On: 10 Jun 2021 09:13:08

SAEID	USA-US120-2020-MRNA-1273-P301000001
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 11:31
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

US3632032 (Prod: Grady Health System)

US3632032

Form: Participant Creation

Generated On: 10 Jun 2021 09:13:08

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:09:44
User entered 'US3632032'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:45:05

US3632032

Form: Participant Creation

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57

US3632032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:20:36
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:30

US3632032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:20:36
User entered '01 SEP 2020'	RWS_ENDPOINT	01 Sep 2020 14:45:06
	ENDPOINT (b) (4)	

US3632032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:20:36
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:30

US3632032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'SCRN'	System	16 Sep 2020 18:00:30

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered (b) (6) 1964'	RWS_ENDPOINT	01 Sep 2020 14:45:07
	ENDPOINT (b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '55'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'YEARS'	System	02 Sep 2020 19:55:11

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '55'	System	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered 'Female (F)'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '1'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered empty.	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:21:49
User entered '0'	Bezuayehu Mandefro	02 Sep 2020 19:55:11
	(b) (4)	

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User entered '1 Sep 2020'	Sarah Wiatrek (b) (4)	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Sep 2020'	System	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2020'	System	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User entered 'Amendment 3 (3)'	Sarah Wiatrek (b) (4)	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User entered 'No (N)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:10
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 17:59:52

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:22:24
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	16 Sep 2020 18:00:10
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	16 Sep 2020 17:59:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:45:06

US3632032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1'	System	16 Sep 2020 18:00:17

US3632032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:17

US3632032

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:13:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 20:22:45
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 17:58:58

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:24:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:24:51
Data point term sent to Coder	System	22 Sep 2020 18:23:30
User entered 'Hypertension'	Aastha KC (b) (4)	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 1996'	Aastha KC (b) (4)	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 1996'	System	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1996'	System	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:22:55

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:24:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:24:51
Data point term sent to Coder	System	22 Sep 2020 18:24:31
User entered 'Atrial Fibrillation'	Aastha KC (b) (4)	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 1996'	Aastha KC (b) (4)	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 1996'	System	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1996'	System	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:23:49

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:21:46
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Participant withdrew consent.' (Site from DM).	Kelly Likos (b) (4)	23 Oct 2020 14:34:05
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:32:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:26:41
Data point term sent to Coder	System	22 Sep 2020 18:25:33
User entered 'Gallbladder Removed'	Aastha KC (b) (4)	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 1998'	Aastha KC (b) (4)	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 1998'	Aastha KC (b) (4)	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 1998'	System	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1998'	System	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 1998'	System	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1998'	System	22 Sep 2020 18:24:34

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:27:43
Data point term sent to Coder	System	22 Sep 2020 18:26:35
User entered 'Sleeve Gastrectomy'	Aastha KC (b) (4)	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Oct 2013'	Aastha KC (b) (4)	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Oct 2013'	Aastha KC (b) (4)	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Oct 2013'	System	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2013'	System	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Oct 2013'	System	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2013'	System	22 Sep 2020 18:25:57

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per MM, please include the underlying condition that led to the procedure' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:13:01
Query 'Per MM, please include the underlying condition that led to the procedure' answered with 'Participant withdrew consent.' (Site from DM).	Kelly Likos (b) (4)	23 Oct 2020 14:34:24
User opened query 'Per MM, please include the underlying condition that led to the procedure' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:03:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 18:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 18:28:42
Data point term sent to Coder	System	22 Sep 2020 18:27:39
User entered 'Cardiac Ablation'	Aastha KC (b) (4)	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Oct 2012'	Aastha KC (b) (4)	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Apr 2013'	Aastha KC (b) (4)	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Oct 2012'	System	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2012'	System	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Apr 2013'	System	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2013'	System	22 Sep 2020 18:27:27

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:55:53
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Participant withdrew consent.' (Site from DM).	Kelly Likos (b) (4)	23 Oct 2020 14:34:41
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:33:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingo-oophorectomy unilateral, LLT: Right salpingo-oophorectomy - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 10:48:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 10:48:50
Data point term sent to Coder	System	22 Sep 2020 18:28:39
User entered 'Right Ovary and Tube Removed'	Aastha KC (b) (4)	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Apr 1993'	Aastha KC (b) (4)	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Apr 1993'	Aastha KC (b) (4)	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Apr 1993'	System	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1993'	System	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Apr 1993'	System	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1993'	System	22 Sep 2020 18:28:21

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Investigations, HLT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy R knee - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 18:30:48
Data point term sent to Coder	System	22 Sep 2020 18:29:45
User entered 'Right Knee Arthroscopy'	Aastha KC (b) (4)	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jun 1995'	Aastha KC (b) (4)	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Oct 1997'	Aastha KC (b) (4)	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jun 1995'	System	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1995'	System	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Oct 1997'	System	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1997'	System	22 Sep 2020 18:29:37

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 18:51:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 18:51:47
Data point term sent to Coder	System	22 Sep 2020 18:31:49
User entered 'Anemia (low-grade) (two low to be treatable)'	Aastha KC (b) (4)	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 2010'	Aastha KC (b) (4)	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 2010'	System	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2010'	System	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:31:33

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:34:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:33:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:51:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:51:48
Data point term sent to Coder	System	22 Sep 2020 18:32:51
User entered 'Mild Asthma (on inhaler as needed rarely needed)'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Query 'Per source, start date is listed as "1/2000". Please update EDC to reflect accurate dating convention. ' canceled (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 16:34:39
User opened query 'Per source, start date is listed as "1/2000". Please update EDC to reflect accurate dating convention. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 16:33:50
User entered '01 Jan 2000'	Aastha KC (b) (4)	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:34:41
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:33:53
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:34:42
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:33:54
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:33:56
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:34:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:33:58
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 2000'	System	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2000'	System	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:32:48

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Pollen allergy - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 18:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 18:49:41
Data point term sent to Coder	System	22 Sep 2020 18:34:53
User entered 'Allergies (Pollen/Hay Fever)'	Aastha KC (b) (4)	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '1'	Aastha KC (b) (4)	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Sep 2020 18:34:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 18:34:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:34:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Sep 2020 18:33:59
User entered empty.	System	22 Sep 2020 18:33:59
	Aastha KC (b) (4)	22 Sep 2020 18:33:59
	(b) (4)	

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:33:59

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 19:30:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 19:30:59
Data point term sent to Coder	System	25 Sep 2020 19:29:45
User entered 'Severe Obesity'	Isaac Perez (b) (4)	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Isaac Perez (b) (4)	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '1'	Isaac Perez (b) (4)	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Isaac Perez (b) (4)	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Isaac Perez (b) (4)	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Isaac Perez (b) (4)	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	25 Sep 2020 19:29:05

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 12:47:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 12:47:32
Data point term sent to Coder	System	19 Oct 2020 12:46:42
User entered 'Menopause'	Isaac Perez (b) (4)	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 2019'	Isaac Perez (b) (4)	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Isaac Perez (b) (4)	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Isaac Perez (b) (4)	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Isaac Perez (b) (4)	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Isaac Perez (b) (4)	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'Jan 2019'	System	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '2019'	System	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	19 Oct 2020 12:46:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '1 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '11:24'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1 Sep 2020 11:24'	System	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '163' cm	(b) (4) Aastha KC (b) (4)	22 Sep 2020 18:03:13
DataPoint set to visible.	(b) (4) System	16 Sep 2020 18:00:17

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '308' lb	Aastha KC (b) (4)	22 Sep 2020 18:03:13
DataPoint set to visible.	System	16 Sep 2020 18:00:17

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '52.69299'	System	22 Sep 2020 18:03:13
DataPoint set to visible.	System	16 Sep 2020 18:00:17

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'kg/m2'	System	22 Sep 2020 18:03:13
DataPoint set to visible.	System	16 Sep 2020 18:00:17

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '98.2' F	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Oral (Oral)'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '69'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'bpm'	System	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '14'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'breaths/min'	System	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Re-query: Per CDM: Response noted as "Abnormal-CS" ,however, If CS, please add the event to the adverse event form. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 10:32:19
Query 'Re-query: Per CDM: Response noted as "Abnormal-CS" ,however, If CS, please add the event to the adverse event form. Thank you' answered with 'Cannot be inputted into adverse event form due to occurring before exposure.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	23 Sep 2020 20:21:27
User opened query 'Re-query: Per CDM: Response noted as "Abnormal-CS" ,however, If CS, please add the event to the adverse event form. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 06:47:51
User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 06:47:09
Query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' answered with 'Abnormal, CS- Asked to follow up with PCP to get accurate measurement ' (Site from System).	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:04:20
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	22 Sep 2020 18:03:13
User entered '188'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'mmHg'	System	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '84'	Aastha KC (b) (4)	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'mmHg'	System	22 Sep 2020 18:03:13

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09

US3632032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09

US3632032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:04:48

US3632032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	22 Sep 2020 18:05:12
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	22 Sep 2020 18:05:12
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:05:12
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:05:12
User entered '01 Sep 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:05:12
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:04:48
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:04:48
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	22 Sep 2020 18:04:48
User entered '01 Sep 1998'	Aastha KC (b) (4)	22 Sep 2020 18:04:48

US3632032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:06:18

US3632032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:06:18

US3632032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per CDM Re-Query: Please note that Menopause (post-menopause) is part of the subject's medical history. Please add. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:51:52
Query 'Per CDM Re-Query: Please note that Menopause (post-menopause) is part of the subject's medical history. Please add. Thank you' answered with 'Updated Condition' (Site from DM).	Isaac Perez (b) (4)	19 Oct 2020 12:44:29
User opened query 'Per CDM Re-Query: Please note that Menopause (post-menopause) is part of the subject's medical history. Please add. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:25:39
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:25:39
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'menopause does not need to be entered into medical history. only the date of last menstruation according to the CRF completion guideline' (Site from DM).	Bezuayehu Mandefro (b) (4)	07 Oct 2020 12:31:18
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 05:21:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Aastha KC (b) (4)	22 Sep 2020 18:06:18

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:06:18

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:06:18

US3632032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:06:18

US3632032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '01 Jan 2018'	Aastha KC (b) (4)	22 Sep 2020 18:06:18

US3632032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:08

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:06:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Goes to the grocery store, nail salon, volunteers at polling place and goes to the movies once a month'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '1'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:08:15

US3632032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:53

US3632032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 Sep 2020'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:53

US3632032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:00:53

US3632032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:13:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'VISIT1'	System	16 Sep 2020 18:00:53

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 16:50:03

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '146180'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 16:50:03

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 16:50:03

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:10:52

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:10:52

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:10:52

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:10:52

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:10:52

US3632032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:10:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:54:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:54:43

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	22 Sep 2020 18:18:33
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	22 Sep 2020 18:18:33
User entered '63.5' in reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	22 Sep 2020 18:16:08
User entered '63.5' cm	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '308' lb	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	22 Sep 2020 18:18:33
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	22 Sep 2020 18:18:33
User entered '63.5' in reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	22 Sep 2020 18:16:08
User entered '63.5' cm	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '308' lb	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User accepted default value 'Pre-Dose (PREDOSE)'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '12:22'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '16 Sep 2020 12:22'	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 10:38:07
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Corrected error in units.' (Site from System).	Isaac Perez (b) (4) (b) (4)	23 Sep 2020 20:22:20
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Sep 2020 20:22:09
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Sep 2020 20:22:09
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	23 Sep 2020 20:22:09
User entered '96.0' F reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	23 Sep 2020 20:22:09
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Sep 2020 18:16:08
User entered '96.0' C	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Oral (Oral)'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '82'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'bpm'	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '22'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'breaths/min'	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '155'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'mmHg'	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '84'	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'mmHg'	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	22 Sep 2020 18:18:33
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	22 Sep 2020 18:18:33
User entered '63.5' in reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	22 Sep 2020 18:16:08
User entered '63.5' cm	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '308' lb	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User accepted default value 'Post-Dose (POSTDOSE)'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Sep 2020 18:18:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 18:18:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Sep 2020 18:16:08
User entered empty.	System	22 Sep 2020 18:16:08
	Aastha KC (b) (4)	22 Sep 2020 18:16:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 Sep 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '14:15' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '16 Sep 2020 14:15'	System	22 Sep 2020 18:18:33
User entered empty.	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Sep 2020 20:23:01
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	23 Sep 2020 20:23:01
User entered '97.2' F reason for change: Data Entry Error	Isaac Perez (b) (4)	23 Sep 2020 20:23:01
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Sep 2020 18:18:33
User entered '97.2' C reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '72' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'bpm'	System	22 Sep 2020 18:18:33
User entered empty.	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '12' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'breaths/min'	System	22 Sep 2020 18:18:33
User entered empty.	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '182' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'mmHg'	System	22 Sep 2020 18:18:33
User entered empty.	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '107' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:18:33
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'mmHg'	System	22 Sep 2020 18:18:33
User entered empty.	System	22 Sep 2020 18:16:08

US3632032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:19:06

US3632032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:19:06

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 Sep 2020'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '13:42'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '16 Sep 2020 13:42'	System	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Left Arm (LEFT ARM)'	Sarah Wiatrek (b) (4)	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'ONCE'	System	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:08

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 18:01:25

US3632032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:20:15

US3632032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '16 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:20:15

US3632032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:37:27
User entered '12:58'	Aastha KC (b) (4)	22 Sep 2020 18:20:15

US3632032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '16 Sep 2020 12:58'	System	22 Sep 2020 18:20:15

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:13:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '16 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:13:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:13:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:13:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '13:02'	Aastha KC (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '16 Sep 2020 13:02'	System	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:13:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:13:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:13:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered empty.	System	22 Sep 2020 18:20:46

US3632032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:21:09

US3632032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:31:09
User entered '1'	System	22 Sep 2020 18:21:09

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:20:32', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ec5f7d2d-df4b-4658-86af-b697ab915598'	System	16 Sep 2020 18:20:58
User entered 'Yes (Y)'	System	16 Sep 2020 18:20:58

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:20:40', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ec5f7d2d-df4b-4658-86af-b697ab915598'	System	16 Sep 2020 18:20:58
User entered '97.2'	System	16 Sep 2020 18:20:58

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:20:46', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ec5f7d2d-df4b-4658-86af-b697ab915598'	System	16 Sep 2020 18:20:58
User entered 'No (N)'	System	16 Sep 2020 18:20:58

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:20:54', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ec5f7d2d-df4b-4658-86af-b697ab915598'	System	16 Sep 2020 18:20:58
User entered '16 Sep 2020 14:20'	System	16 Sep 2020 18:20:58

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 14:02'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 16:32'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:15:19', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'b8e266a2-c7d2-4720-b579-2d34737eb465'	System	17 Sep 2020 01:15:44
User entered 'Yes (Y)'	System	17 Sep 2020 01:15:44

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:15:26', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'b8e266a2-c7d2-4720-b579-2d34737eb465'	System	17 Sep 2020 01:15:44
User entered '97.6'	System	17 Sep 2020 01:15:44

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:15:31', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'b8e266a2-c7d2-4720-b579-2d34737eb465'	System	17 Sep 2020 01:15:44
User entered 'No (N)'	System	17 Sep 2020 01:15:44

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:15:40', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'b8e266a2-c7d2-4720-b579-2d34737eb465'	System	17 Sep 2020 01:15:44
User entered '16 Sep 2020 21:15'	System	17 Sep 2020 01:15:44

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 17:27'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 2'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:54:57', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ee4f03ff-e444-4bd2-a032-0c5964170daf'	System	18 Sep 2020 00:57:18
User entered 'Yes (Y)'	System	18 Sep 2020 00:57:18

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:56:57', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ee4f03ff-e444-4bd2-a032-0c5964170daf'	System	18 Sep 2020 00:57:18
User entered '98.5'	System	18 Sep 2020 00:57:18

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:57:01', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ee4f03ff-e444-4bd2-a032-0c5964170daf'	System	18 Sep 2020 00:57:18
User entered 'No (N)'	System	18 Sep 2020 00:57:18

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:57:12', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'ee4f03ff-e444-4bd2-a032-0c5964170daf'	System	18 Sep 2020 00:57:18
User entered '17 Sep 2020 20:57'	System	18 Sep 2020 00:57:18

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 3'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:18', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '4b4587a5-33ce-4d98-b4fc-e34f2d730b3a'	System	19 Sep 2020 00:57:36
User entered 'Yes (Y)'	System	19 Sep 2020 00:57:36

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:23', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '4b4587a5-33ce-4d98-b4fc-e34f2d730b3a'	System	19 Sep 2020 00:57:36
User entered '98.2'	System	19 Sep 2020 00:57:36

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:27', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '4b4587a5-33ce-4d98-b4fc-e34f2d730b3a'	System	19 Sep 2020 00:57:36
User entered 'No (N)'	System	19 Sep 2020 00:57:36

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:33', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '4b4587a5-33ce-4d98-b4fc-e34f2d730b3a'	System	19 Sep 2020 00:57:36
User entered '18 Sep 2020 20:57'	System	19 Sep 2020 00:57:36

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 4'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:16:43', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '8717b448-97e3-4ee0-b899-0e4672d5e5bb'	System	20 Sep 2020 00:17:05
User entered 'Yes (Y)'	System	20 Sep 2020 00:17:05

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:16:49', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '8717b448-97e3-4ee0-b899-0e4672d5e5bb'	System	20 Sep 2020 00:17:05
User entered '98.5'	System	20 Sep 2020 00:17:05

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:16:52', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '8717b448-97e3-4ee0-b899-0e4672d5e5bb'	System	20 Sep 2020 00:17:05
User entered 'No (N)'	System	20 Sep 2020 00:17:05

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:16:58', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '8717b448-97e3-4ee0-b899-0e4672d5e5bb'	System	20 Sep 2020 00:17:05
User entered '19 Sep 2020 20:16'	System	20 Sep 2020 00:17:05

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 5'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:28:33', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'cededf2f-5d19-48a3-aa3e-64d6f42657cc'	System	21 Sep 2020 00:28:55
User entered 'Yes (Y)'	System	21 Sep 2020 00:28:55

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:28:38', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'cededf2f-5d19-48a3-aa3e-64d6f42657cc' User entered '98.3'	System	21 Sep 2020 00:28:55
	System	21 Sep 2020 00:28:55

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:28:43', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'cededf2f-5d19-48a3-aa3e-64d6f42657cc'	System	21 Sep 2020 00:28:55
User entered 'No (N)'	System	21 Sep 2020 00:28:55

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:28:49', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'cededf2f-5d19-48a3-aa3e-64d6f42657cc'	System	21 Sep 2020 00:28:55
User entered '20 Sep 2020 20:28'	System	21 Sep 2020 00:28:55

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 6'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:00', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '23885d73-1bdb-4b5e-8896-efc84af85c28'	System	22 Sep 2020 01:14:20
User entered 'Yes (Y)'	System	22 Sep 2020 01:14:20

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:06', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '23885d73-1bdb-4b5e-8896-efc84af85c28'	System	22 Sep 2020 01:14:20
User entered '98.7'	System	22 Sep 2020 01:14:20

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:09', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '23885d73-1bdb-4b5e-8896-efc84af85c28'	System	22 Sep 2020 01:14:20
User entered 'No (N)'	System	22 Sep 2020 01:14:20

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:15', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '23885d73-1bdb-4b5e-8896-efc84af85c28'	System	22 Sep 2020 01:14:20
User entered '21 Sep 2020 21:14'	System	22 Sep 2020 01:14:20

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 7'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:20', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'd67e51b5-03a1-4d12-9413-ddfbac2ff450'	System	23 Sep 2020 01:29:39
User entered 'Yes (Y)'	System	23 Sep 2020 01:29:39

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:28', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'd67e51b5-03a1-4d12-9413-ddfbac2ff450'	System	23 Sep 2020 01:29:39
User entered '98.0'	System	23 Sep 2020 01:29:39

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:32', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'd67e51b5-03a1-4d12-9413-ddfbac2ff450'	System	23 Sep 2020 01:29:39
User entered 'No (N)'	System	23 Sep 2020 01:29:39

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:36', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'd67e51b5-03a1-4d12-9413-ddfbac2ff450'	System	23 Sep 2020 01:29:39
User entered '22 Sep 2020 21:29'	System	23 Sep 2020 01:29:39

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:21:41', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '9c851e03-9dfa-4000-b491-d51350e6a48d'	System	16 Sep 2020 18:22:16
User entered 'None (1)'	System	16 Sep 2020 18:22:16

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:21:47', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '9c851e03-9dfa-4000-b491-d51350e6a48d'	System	16 Sep 2020 18:22:16
User entered 'No (N)'	System	16 Sep 2020 18:22:16

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:21:54', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '9c851e03-9dfa-4000-b491-d51350e6a48d'	System	16 Sep 2020 18:22:16
User entered 'No (N)'	System	16 Sep 2020 18:22:16

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:04', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '9c851e03-9dfa-4000-b491-d51350e6a48d'	System	16 Sep 2020 18:22:16
User entered 'None (1)'	System	16 Sep 2020 18:22:16

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:12', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '9c851e03-9dfa-4000-b491-d51350e6a48d'	System	16 Sep 2020 18:22:16
User entered '16 Sep 2020 14:22'	System	16 Sep 2020 18:22:16

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 14:02'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 16:32'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:15:55', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f313789-9622-465c-85d2-5544aa4ebd72'	System	17 Sep 2020 01:16:44
User entered 'None (1)'	System	17 Sep 2020 01:16:44

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:15:59', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f313789-9622-465c-85d2-5544aa4ebd72'	System	17 Sep 2020 01:16:44
User entered 'No (N)'	System	17 Sep 2020 01:16:44

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:16:07', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f313789-9622-465c-85d2-5544aa4ebd72'	System	17 Sep 2020 01:16:44
User entered 'No (N)'	System	17 Sep 2020 01:16:44

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:16:32', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f313789-9622-465c-85d2-5544aa4ebd72'	System	17 Sep 2020 01:16:44
User entered 'None (1)'	System	17 Sep 2020 01:16:44

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:16:39', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f313789-9622-465c-85d2-5544aa4ebd72'	System	17 Sep 2020 01:16:44
User entered '16 Sep 2020 21:16'	System	17 Sep 2020 01:16:44

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 17:27'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 2'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:57:36', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '32939d64-4129-4f64-9a51-259eb26bf5c8'	System	18 Sep 2020 00:58:08
User entered 'None (1)'	System	18 Sep 2020 00:58:08

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:57:40', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '32939d64-4129-4f64-9a51-259eb26bf5c8'	System	18 Sep 2020 00:58:08
User entered 'No (N)'	System	18 Sep 2020 00:58:08

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:57:43', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '32939d64-4129-4f64-9a51-259eb26bf5c8'	System	18 Sep 2020 00:58:08
User entered 'No (N)'	System	18 Sep 2020 00:58:08

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:57:58', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '32939d64-4129-4f64-9a51-259eb26bf5c8'	System	18 Sep 2020 00:58:08
User entered 'None (1)'	System	18 Sep 2020 00:58:08

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:06', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '32939d64-4129-4f64-9a51-259eb26bf5c8'	System	18 Sep 2020 00:58:08
User entered '17 Sep 2020 20:58'	System	18 Sep 2020 00:58:08

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 3'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:42', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '77feb582-cd9b-49ce-9147-a5d58d593a4a'	System	19 Sep 2020 00:58:07
User entered 'None (1)'	System	19 Sep 2020 00:58:07

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:46', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '77feb582-cd9b-49ce-9147-a5d58d593a4a'	System	19 Sep 2020 00:58:07
User entered 'No (N)'	System	19 Sep 2020 00:58:07

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:49', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '77feb582-cd9b-49ce-9147-a5d58d593a4a'	System	19 Sep 2020 00:58:07
User entered 'No (N)'	System	19 Sep 2020 00:58:07

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:57:57', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '77feb582-cd9b-49ce-9147-a5d58d593a4a'	System	19 Sep 2020 00:58:07
User entered 'None (1)'	System	19 Sep 2020 00:58:07

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:02', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '77feb582-cd9b-49ce-9147-a5d58d593a4a'	System	19 Sep 2020 00:58:07
User entered '18 Sep 2020 20:58'	System	19 Sep 2020 00:58:07

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 4'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:09', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '31c9c2a7-e1b5-4a44-9377-144c2b8a5206'	System	20 Sep 2020 00:19:42
User entered 'None (1)'	System	20 Sep 2020 00:19:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:12', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '31c9c2a7-e1b5-4a44-9377-144c2b8a5206'	System	20 Sep 2020 00:19:42
User entered 'No (N)'	System	20 Sep 2020 00:19:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:15', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '31c9c2a7-e1b5-4a44-9377-144c2b8a5206'	System	20 Sep 2020 00:19:42
User entered 'No (N)'	System	20 Sep 2020 00:19:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:29', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '31c9c2a7-e1b5-4a44-9377-144c2b8a5206'	System	20 Sep 2020 00:19:42
User entered 'None (1)'	System	20 Sep 2020 00:19:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:36', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '31c9c2a7-e1b5-4a44-9377-144c2b8a5206'	System	20 Sep 2020 00:19:42
User entered '19 Sep 2020 20:18'	System	20 Sep 2020 00:19:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 5'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:29:08', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '40d6ef04-38f4-48d0-b1ae-de380e21ff1c'	System	21 Sep 2020 00:29:42
User entered 'None (1)'	System	21 Sep 2020 00:29:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:29:24', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '40d6ef04-38f4-48d0-b1ae-de380e21ff1c'	System	21 Sep 2020 00:29:42
User entered 'No (N)'	System	21 Sep 2020 00:29:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:29:28', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '40d6ef04-38f4-48d0-b1ae-de380e21ff1c'	System	21 Sep 2020 00:29:42
User entered 'No (N)'	System	21 Sep 2020 00:29:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:29:32', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '40d6ef04-38f4-48d0-b1ae-de380e21ff1c'	System	21 Sep 2020 00:29:42
User entered 'None (1)'	System	21 Sep 2020 00:29:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:29:39', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '40d6ef04-38f4-48d0-b1ae-de380e21ff1c'	System	21 Sep 2020 00:29:42
User entered '20 Sep 2020 20:29'	System	21 Sep 2020 00:29:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 6'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:27', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '59f177aa-2727-489a-84dd-7375bed1f27d'	System	22 Sep 2020 01:14:42
User entered 'None (1)'	System	22 Sep 2020 01:14:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:29', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '59f177aa-2727-489a-84dd-7375bed1f27d'	System	22 Sep 2020 01:14:42
User entered 'No (N)'	System	22 Sep 2020 01:14:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:32', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '59f177aa-2727-489a-84dd-7375bed1f27d'	System	22 Sep 2020 01:14:42
User entered 'No (N)'	System	22 Sep 2020 01:14:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:34', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '59f177aa-2727-489a-84dd-7375bed1f27d'	System	22 Sep 2020 01:14:42
User entered 'None (1)'	System	22 Sep 2020 01:14:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:40', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '59f177aa-2727-489a-84dd-7375bed1f27d'	System	22 Sep 2020 01:14:42
User entered '21 Sep 2020 21:14'	System	22 Sep 2020 01:14:42

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 7'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:44', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '29f284cc-a51f-4700-a610-fe91d4bf3747'	System	23 Sep 2020 01:30:05
User entered 'None (1)'	System	23 Sep 2020 01:30:05

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:49', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '29f284cc-a51f-4700-a610-fe91d4bf3747'	System	23 Sep 2020 01:30:05
User entered 'No (N)'	System	23 Sep 2020 01:30:05

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:52', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '29f284cc-a51f-4700-a610-fe91d4bf3747'	System	23 Sep 2020 01:30:05
User entered 'No (N)'	System	23 Sep 2020 01:30:05

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:29:57', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '29f284cc-a51f-4700-a610-fe91d4bf3747'	System	23 Sep 2020 01:30:05
User entered 'None (1)'	System	23 Sep 2020 01:30:05

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:01', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '29f284cc-a51f-4700-a610-fe91d4bf3747'	System	23 Sep 2020 01:30:05
User entered '22 Sep 2020 21:30'	System	23 Sep 2020 01:30:05

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:21', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'None (0)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:25', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'None (0)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:29', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'None (0)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:33', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'None (0)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:38', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'None (0)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:42', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'None (0)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:22:54', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered 'No (N)'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T14:23:01', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '15ce7cdf-9e67-4fb0-921e-09fbffb2d8cc'	System	16 Sep 2020 18:23:05
User entered '16 Sep 2020 14:23'	System	16 Sep 2020 18:23:05

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 14:02'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 16:32'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:16:54', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'None (0)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:16:59', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'None (0)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:17:03', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'None (0)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:17:16', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'None (0)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:17:19', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'None (0)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:17:22', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'None (0)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:19:22', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered 'Yes (Y)'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-16T21:22:47', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: 'f9ee2c36-af2f-41f7-9c1d-481d42ac53a9'	System	17 Sep 2020 01:23:49
User entered '16 Sep 2020 21:22'	System	17 Sep 2020 01:23:49

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '16 Sep 2020 17:27'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 2'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:19', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered 'No interference with activity (1)'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:24', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered 'None (0)'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:27', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed' User entered 'None (0)'	System	18 Sep 2020 00:58:55
	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:32', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered 'None (0)'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:35', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered 'None (0)'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:38', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered 'None (0)'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:44', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered 'No (N)'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-17T20:58:52', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '814ce236-ed80-4366-adb9-69daff4972ed'	System	18 Sep 2020 00:58:55
User entered '17 Sep 2020 20:58'	System	18 Sep 2020 00:58:55

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 3'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:07', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'None (0)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:11', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'None (0)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:14', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'None (0)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:16', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'None (0)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:20', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'None (0)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:24', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'None (0)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:30', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered 'No (N)'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-18T20:58:35', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '17fe4398-1292-428a-a672-64af00330e0e'	System	19 Sep 2020 00:58:37
User entered '18 Sep 2020 20:58'	System	19 Sep 2020 00:58:37

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 4'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:43', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'None (0)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:18:47', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'None (0)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:19:01', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'None (0)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:19:05', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'No interference with activity (1)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:19:08', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'None (0)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:19:10', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'None (0)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:19:13', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered 'No (N)'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-19T20:19:30', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '7c0ad0cb-e62f-449d-a7fc-8cdcb66e1760'	System	20 Sep 2020 00:20:34
User entered '19 Sep 2020 20:19'	System	20 Sep 2020 00:20:34

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 5'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:15', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a'	System	21 Sep 2020 00:30:39
User entered 'None (0)'	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:18', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a' User entered 'None (0)'	System	21 Sep 2020 00:30:39
	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:20', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a'	System	21 Sep 2020 00:30:39
User entered 'None (0)'	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:22', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a' User entered 'None (0)'	System	21 Sep 2020 00:30:39
	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:25', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a'	System	21 Sep 2020 00:30:39
User entered 'None (0)'	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:27', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a'	System	21 Sep 2020 00:30:39
User entered 'None (0)'	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:29', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a'	System	21 Sep 2020 00:30:39
User entered 'No (N)'	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-20T20:30:35', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '095c2076-52c3-4409-95a5-1529a07df42a'	System	21 Sep 2020 00:30:39
User entered '20 Sep 2020 20:30'	System	21 Sep 2020 00:30:39

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 6'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:45', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'None (0)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:47', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'None (0)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:49', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'None (0)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:51', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'None (0)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:54', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'None (0)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:57', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'None (0)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:14:59', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered 'No (N)'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-21T21:15:06', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '3f045aba-079f-48de-8300-1152aef511d8'	System	22 Sep 2020 01:15:28
User entered '21 Sep 2020 21:15'	System	22 Sep 2020 01:15:28

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
Data entry locked.	System	16 Sep 2020 18:01:25
User entered 'Day 7'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:07', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'None (0)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:10', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'None (0)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:13', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'None (0)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:17', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'None (0)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:19', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'None (0)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:21', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'None (0)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

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 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:24', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered 'No (N)'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9c581a4964afe3f1)', Time: '2020-09-22T21:30:28', User OID: 'PatientReportedOutcome (US3632032)', ODM File OID: '129dd6bb-18b2-407e-a530-629f0b2de9e6'	System	23 Sep 2020 01:30:30
User entered '22 Sep 2020 21:30'	System	23 Sep 2020 01:30:30

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:01:25

US3632032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:13:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:53:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:01:25

US3632032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	23 Sep 2020 17:11:21

US3632032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '23 Sep 2020'	Sarah Wiatrek (b) (4)	23 Sep 2020 17:11:21

US3632032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	23 Sep 2020 17:11:21

US3632032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Sarah Wiatrek (b) (4)	23 Sep 2020 17:11:21

US3632032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	23 Sep 2020 17:11:26

US3632032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	23 Sep 2020 17:11:26

US3632032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	30 Sep 2020 17:49:14

US3632032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '30 Sep 2020'	Sarah Wiatrek (b) (4)	30 Sep 2020 17:49:14

US3632032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	30 Sep 2020 17:49:14

US3632032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	Sarah Wiatrek (b) (4)	30 Sep 2020 17:49:14

US3632032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	30 Sep 2020 17:49:20

US3632032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	30 Sep 2020 17:49:20

US3632032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	07 Oct 2020 13:44:06
	(b) (4)	

US3632032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '07 Oct 2020'	(b) (4) Bezuayehu Mandefro (b) (4)	07 Oct 2020 13:44:06

US3632032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Bezuayehu Mandefro (b) (4)	07 Oct 2020 13:44:06

US3632032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered empty.	(b) (4) Bezuayehu Mandefro	07 Oct 2020 13:44:06
	(b) (4)	

US3632032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	07 Oct 2020 13:56:16
	(b) (4)	

US3632032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	07 Oct 2020 13:56:16

US3632032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:13:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:42:12
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:34:59

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:28
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	17 Sep 2020 15:07:17

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Accelerated and malignant hypertension, PT: Hypertensive emergency, LLT: Hypertensive emergency - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 20:59:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 20:59:21
Data point term sent to Coder	System	16 Sep 2020 20:58:00
User entered 'hypertensive emergency'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '16 Sep 2020'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:55:19
User entered '14:15' reason for change: Data Entry Error	Christina Bacher (b) (4)	10 Nov 2020 13:37:28
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:33
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '13:15'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '16 Sep 2020 14:15'	System	10 Nov 2020 13:37:28
User entered '16 Sep 2020 13:15'	System	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)' reason for change: New Information	Sarah Wiatrek (b) (4)	18 Sep 2020 20:27:16
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Sep 2020 20:27:16
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	18 Sep 2020 20:27:16
User entered '18 Sep 2020' reason for change: New Information	Sarah Wiatrek (b) (4)	18 Sep 2020 20:27:16
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Sep 2020 20:26:27
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57
	(b) (4)	

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:55:21
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 20:27:42
User entered '16:27' reason for change: New Information	Sarah Wiatrek (b) (4)	18 Sep 2020 20:27:42
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 20:27:16
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '18 Sep 2020 16:27'	System	18 Sep 2020 20:27:42
User entered empty.	System	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Grade 4 (Grade 4)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '1'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

US3632032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Related (NOT RELATED)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Related (NOT RELATED)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'None (NONE)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 07:44:31
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Recorded the increase in medication as per con med #6' (Site from DM).	Isaac Perez (b) (4)	19 Oct 2020 12:49:22
User entered '0' reason for change: New Information	Isaac Perez (b) (4)	19 Oct 2020 12:48:59
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 10:51:34
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 20:58:30
User entered '1' reason for change: New Information	Sarah Wiatrek (b) (4)	16 Sep 2020 20:58:30
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 20:57:57
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '1' reason for change: New Information	Isaac Perez (b) (4)	19 Oct 2020 12:48:59
User entered '0'	(b) (4)	
	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sarah Wiatrek (b) (4)	18 Sep 2020 20:26:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User closed query 'PV Query: It was noted the subject managed her BP with additional medications. Please provide treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), if known. If unknown please state so.	(b) (4), (b) (6)	28 Sep 2020 12:20:07
' (Site from Safety).		
User closed query 'PV Query: At event resolution, did the subject's blood pressure normalize? Please provide blood pressure measurements at event resolution if available. ' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 12:19:51
User closed query 'PV Query: In addition to the extremely high blood pressure, please confirm if the subject exhibited any other signs or symptoms at the onset of Hypertensive emergency. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 12:19:49
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. Did the subject have a history of hypertension? ' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 12:19:48
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 12:19:46
User closed query 'PV Query: Please clarify if there were any risk factors and or etiology for the event. ' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 12:19:43
Query 'PV Query: Please clarify if there were any risk factors and or etiology for the event. ' answered with 'Participant has previous history of hypertension and severe obesity. These pre-existing conditions have been added to Med Hx page.' (Site from Safety).	Isaac Perez (b) (4)	25 Sep 2020 19:31:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' answered with 'This information has already been included.' (Site from Safety).	Isaac Perez (b) (4)	25 Sep 2020 19:27:41
Query 'PV Query: It was noted the subject managed her BP with additional medications. Please provide treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), if known. If unknown please state so.	Isaac Perez (b) (4)	25 Sep 2020 19:27:28
' answered with 'Concomitant medications have been updated to reflect change described above.' (Site from Safety).		
Query 'PV Query: At event resolution, did the subject's blood pressure normalize? Please provide blood pressure measurements at event resolution if available. ' answered with 'At resolution, blood pressure normalized to participant's usual levels; included this information in the narrative section.' (Site from Safety).	Isaac Perez (b) (4)	25 Sep 2020 19:25:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ASKED BY STUDY STAFF TO EVALUATE PATIENT FOR EXTREMELY HIGH BP 30MIN POST-VACCINE. PRE-VACCINE BP 155/84; 30 MIN POST VACCINE BP 182/107 14:15; 179/106 AT 14:47 AND 220/113 AT 15:40. RECOMMENDED THAT PATIENT GO TO ED. ADVISED PATIENT OF RISKS OF END ORGAN DAMAGE, STROKE, VISION LOSS AND MI. PATIENT IS AN RN AND UNDERSTOOD ALL RISKS. CONTACTED PATIENT'S CARDIOLOGIST WHO STATED PATIENT WITH MEDICAL NON-COMPLIANCE AND ALSO RECOMMENDED PATIENT GO TO ED. DISCUSSED WITH PATIENT WHO REMAINED ASYMPTOMATIC. PATIENT REFUSED 911 CALL AND ED ADMISSION AND OPTED TO GO HOME AND MANAGE HER BP WITH ADDITIONAL MEDICATIONS. SHE WILL BE FOLLOWED UP PER PROTOCOL BY STUDY TEAM. PATIENT STATED SHE IS AN RN AND UNDERSTANDS ALL RISKS AND PLANS TO FOLLOW UP WITH CARDIOLOGIST AS AN OUTPATIENT. FOLLOWED UP WITH PARTICIPANT ON 18 SEP 2020, BLOOD PRESSURE WAS 169/87, WHICH PARTICIPAT VERIFIED WAS WITHIN HER NORMS.' reason for change: Data Entry Error	Isaac Perez (b) (4)	25 Sep 2020 19:25:07
Query 'PV Query: In addition to the extremely high blood pressure, please confirm if the subject exhibited any other signs or symptoms at the onset of Hypertensive emergency. If none, please state so. ' answered with 'Participant was asymptomatic.' (Site from Safety).	Isaac Perez (b) (4)	25 Sep 2020 19:20:58
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. Did the subject have a history of hypertension? ' answered with 'Med Hx shows history of Hypertension.' (Site from Safety).	Isaac Perez (b) (4)	25 Sep 2020 19:20:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was noted the subject managed her BP with additional medications. Please provide treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), if known. If unknown please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:39:57
User opened query 'PV Query: At event resolution, did the subject's blood pressure normalize? Please provide blood pressure measurements at event resolution if available. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:39:40
User opened query 'PV Query: In addition to the extremely high blood pressure, please confirm if the subject exhibited any other signs or symptoms at the onset of Hypertensive emergency. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:39:26
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. Did the subject have a history of hypertension? ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:39:14
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:38:47
User opened query 'PV Query: Please clarify if there were any risk factors and or etiology for the event. ' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:38:31

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Asked by study staff to evaluate patient for extremely high BP 30min post-vaccine. pre-vaccine BP 155/84; 30 min post vaccine bp 182/107 14:15; 179/106 at 14:47 and 220/113 at 15:40. Recommended that patient go to ED. Advised patient of risks of end organ damage, stroke, vision loss and MI. Patient is an RN and understood all risks. Contacted patient's cardiologist who stated patient with medical non-compliance and also recommended patient go to ED. Discussed with patient who remained asymptomatic. Patient refused 911 call and ED admission and opted to go home and manage her BP with additional medications. She will be followed up per protocol by study team. Patient stated she is an RN and understands all risks and plans to follow up with cardiologist as an outpatient.'	Sarah Wiatrek (b) (4)	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	16 Sep 2020 20:57:57

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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)	26 Apr 2021 20:30:57
User entered '1'	System	16 Sep 2020 20:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:13:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:07:19
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:45:23
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:47:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:47:57
Data point term sent to Coder	System	19 Nov 2020 19:43:18
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'updated as worsening and updated narrative ' (Site from DM).	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 19:42:59
DataPoint Un-verified.	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 19:42:34
Coding entries removed.	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 19:42:34
User entered 'ATRIAL FIBRILLATION, worsening' reason for change: Data Entry Error	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 19:42:34

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:12:24
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:03:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:03:53
Data point term sent to Coder	System	07 Oct 2020 15:55:59
User entered 'Atrial Fibrillation'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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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)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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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)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 15:58:46
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 15:55:05
	Bezuayehu Mandefro	
	(b) (4)	

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Generated On: 10 Jun 2021 09:13:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:21:06
Query 'Please confirm start date of AE; the source notes 07Oct2020. Please review and update RDC.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:21:03
User opened query 'Please confirm start date of AE; the source notes 07Oct2020. Please review and update RDC.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:18:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:16:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '01 Oct 2020'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or if it returned to baseline state and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:19:40
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or if it returned to baseline state and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Participant early terminated so they are no longer being followed.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:23:40
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or if it returned to baseline state and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:48:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 15:58:46
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 15:55:05
	Bezuayehu Mandefro	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

US3632032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Related (NOT RELATED)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Related (NOT RELATED)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'None (NONE)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 15:58:46
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 15:55:05
	Bezuayehu Mandefro	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:55:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:10:01
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4) Catherine Abrams (b) (4)	19 Nov 2020 19:42:34
User entered 'per-existing AFib, now increased episodes in frequency and duration.' reason for change: New Information	(b) (4) Catherine Abrams (b) (4)	19 Nov 2020 19:42:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '0'	System	07 Oct 2020 15:55:05

US3632032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '0'	System	07 Oct 2020 15:55:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 10:00:32
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:00:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:12:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:12:02
Data point term sent to Coder	System	07 Oct 2020 15:58:05
User entered 'Migraine'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:05:04
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:59:14
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'This is an unsolicited event. Thanks ' (Site from DM).	Aastha KC (b) (4)	11 Nov 2020 19:23:25
DataPoint Un-verified.	Aastha KC (b) (4)	11 Nov 2020 19:23:08
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	11 Nov 2020 19:23:08
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:00:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:20:47
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:19:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '04 Oct 2020'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 15:58:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 15:57:53
	Bezuayehu Mandefro	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 15:58:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 15:58:31
User entered 'No (N)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:58:31
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 15:57:53
User entered empty.	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 15:58:46
User entered '04 Oct 2020'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 15:58:46
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 15:57:53
	Bezuayehu Mandefro	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

US3632032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Related (NOT RELATED)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Not Related (NOT RELATED)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'None (NONE)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '1'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:58:46
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '0'	System	07 Oct 2020 15:57:53

US3632032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '0'	System	07 Oct 2020 15:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:13:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:22:17
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:21:32

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:41:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:41:46
Data point term sent to Coder	System	22 Sep 2020 18:41:18
User entered 'Lisinopril'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 16:29:43
User entered 'Hypertension'	Aastha KC (b) (4)	22 Sep 2020 18:40:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '10'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'mg (mg)'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'once daily (QD)'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '01 UNK 2000'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	25 Sep 2020 19:26:45
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '16 Sep 2020' reason for change: Data Entry Error	Isaac Perez (b) (4)	25 Sep 2020 19:26:45
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:40:39

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '804 (804)'	System	22 Sep 2020 18:40:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: This Con Med had dose increased on 06Oct2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in the medication. If yes, please add the applicable AE entry or explain the reason for the change in regimen.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:52:32
Query 'Per DM CLR: This Con Med had dose increased on 06Oct2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in the medication. If yes, please add the applicable AE entry or explain the reason for the change in regimen.' answered with 'Participant confirmed a worsening of AFIB symptoms' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 22:50:36
User opened query 'Per DM CLR: This Con Med had dose increased on 06Oct2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in the medication. If yes, please add the applicable AE entry or explain the reason for the change in regimen.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:16:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:45:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:45:00
Data point term sent to Coder	System	22 Sep 2020 18:43:22
User entered 'Metoprolol'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 16:29:43
User entered 'Atrial Fibrillation'	Aastha KC (b) (4)	22 Sep 2020 18:42:40
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '100'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'mg (mg)'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'once daily (QD)'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '01 UNK 1996'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:24:10
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:42:40
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '05 Oct 2020' reason for change: New Information	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:24:10
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '804 (804)'	System	22 Sep 2020 18:42:40

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 23:20:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 23:20:47
Data point term sent to Coder	System	22 Sep 2020 18:44:27
User entered 'Flecainide'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Atrial Fibrillation'	Aastha KC (b) (4)	22 Sep 2020 18:44:20
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '100'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'mg (mg)'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'twice daily (BID)'	Aastha KC (b) (4)	22 Sep 2020 18:44:20
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '01 Apr 2019'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 16:29:43
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:44:20
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '2'	System	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '804 (804)'	System	22 Sep 2020 18:44:20

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 04:43:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	11 Nov 2020 04:43:45
Data point term sent to Coder	System	10 Nov 2020 15:54:39
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 15:54:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 13:41:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	23 Sep 2020 13:41:34
Data point term sent to Coder	System	22 Sep 2020 18:47:34
User entered 'Xopenex Inhaler'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:47:04
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:06:46
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated, participant use inhaler due to mild asthma.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:54:12
User entered 'Mild Asthma' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:54:05
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:35:55
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:27:20
User entered 'General'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '2'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'puff (PUFF)'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 16:29:43
User entered 'as needed (PRN)'	Aastha KC (b) (4)	22 Sep 2020 18:47:04
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 16:29:43
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Aastha KC (b) (4)	22 Sep 2020 18:47:04
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '01 UNK 2010'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 20:23:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 20:23:57
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	23 Sep 2020 20:23:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 18:47:04
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:47:04
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	22 Sep 2020 18:47:04

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 17:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 17:34:43
Data point term sent to Coder	System	06 Jan 2021 17:13:16
Coding entries removed.	Isaac Perez (b) (4)	06 Jan 2021 17:12:54
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:52:38
Data point term sent to Coder	System	22 Sep 2020 18:51:41
User entered 'Cetirizine'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 18:51:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 18:51:09
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Sep 2020 18:51:09
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 18:50:55
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:50:55
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 08:41:13
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' answered with 'Updated Indication' (Site from DM).	Isaac Perez (b) (4) (b) (4)	06 Jan 2021 17:13:02
DataPoint Un-verified.	Isaac Perez (b) (4) (b) (4)	06 Jan 2021 17:12:54
User entered 'Pollen/Hay Fever ALLERGIES' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	06 Jan 2021 17:12:54
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:58:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Allergies'	Aastha KC (b) (4) (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '10'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'mg (mg)'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:30:56
User closed query 'Frequency is noted in the chart as "as needed"; please review and update RDC.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:39:29
Query 'Frequency is noted in the chart as "as needed"; please review and update RDC.' answered with 'as needed, it was a mistake ' (Site from CRA).	Aastha KC (b) (4)	09 Nov 2020 15:42:35
User entered 'as needed (PRN)' reason for change:	(b) (4)	09 Nov 2020 15:42:23
Data Entry Error	(b) (4)	05 Nov 2020 16:47:47
User opened query 'Frequency is noted in the chart as "as needed"; please review and update RDC.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:46:03
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 18:50:55
User entered 'once daily (QD)'	Aastha KC (b) (4)	
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:50:55
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '01 Apr 2020'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 20:24:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 20:24:07
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	23 Sep 2020 20:24:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 18:50:55
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:50:55
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	09 Nov 2020 15:42:23
User entered '1'	System	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	09 Nov 2020 15:42:23
User entered '1'	System	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	09 Nov 2020 15:42:23
User entered '804 (804)'	System	22 Sep 2020 18:50:55

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:54:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:54:38
Data point term sent to Coder	System	22 Sep 2020 18:53:44
User entered 'Lisinopril'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:53:43
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		05 Nov 2020 16:29:43
User entered 'Hypertension'	Aastha KC (b) (4)	22 Sep 2020 18:53:43
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '20'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'mg (mg)'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'once daily (QD)'	Aastha KC (b) (4)	22 Sep 2020 18:53:43
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '16 Sep 2020'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
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)	
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 'participant continued on current dose and subsequently withdrew from study on 22OCT' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:48:49
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 'participant continued on current dose and subsequently withdrew from study on 22OCT' (Site from DM).	Catherine Abrams (b) (4)	19 Nov 2020 19:54:54
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)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:12:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:29:43
	Aastha KC (b) (4)	22 Sep 2020 18:53:43
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Aastha KC (b) (4)	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '804 (804)'	System	22 Sep 2020 18:53:43

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:29:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:27:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:27:16
Data point term sent to Coder	System	07 Oct 2020 15:26:12
User entered 'Metoprolol'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:25:34

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Atrial Fibrillation'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '150'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 15:25:34
	Bezuayehu Mandefro	
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 15:25:34
	Bezuayehu Mandefro	
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Oral (ORAL)'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '06 Oct 2020'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Yes (Y)'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:25:34
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	07 Oct 2020 15:25:34

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '1'	System	07 Oct 2020 15:25:34

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered '804 (804)'	System	07 Oct 2020 15:25:34

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
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)	07 Oct 2020 15:31:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:31:16
Data point term sent to Coder	System	07 Oct 2020 15:30:20
User entered 'Tylenol'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:29:48

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 15:29:48
	Bezuayehu Mandefro	
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User entered 'Migraine'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '650'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User entered 'once (ONCE)'	(b) (4), (b) (6)	07 Oct 2020 15:29:48
	Bezuayehu Mandefro	
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Oral (ORAL)'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '04 Oct 2020' reason for change: Data Entry Error	Bezuayehu Mandefro	07 Oct 2020 16:04:06
	(b) (4)	
User entered '07 Oct 2020'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	Bezuayehu Mandefro	07 Oct 2020 15:29:48
	(b) (4)	

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User entered '04 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:04:06
User entered '07 Oct 2020'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:29:48

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:49:31
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:06:46
DataPoint Un-verified.	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:06:09
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:06:09
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:17:21

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	07 Oct 2020 15:29:48

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:29:48

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:29:48

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	07 Oct 2020 15:29:48

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM BROMIDE/ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 05:52:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 05:52:24
Data point term sent to Coder	System	13 Oct 2020 21:15:27
User entered 'Ipratropium bromide/Albuterol'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'asthma exacerbation'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'unknown'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	05 Nov 2020 16:29:43
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	13 Oct 2020 21:15:39
User entered 'dose is unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 21:15:39
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	13 Oct 2020 21:15:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Un-verified.	(b) (4)	
	Christina Bacher (b) (4)	01 Dec 2020 13:45:54
User entered '01 UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Christina Bacher (b) (4)	01 Dec 2020 13:45:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'un UNK 2019'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:49:39
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:06:38
DataPoint Un-verified.	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:06:33
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:06:33
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:17:46

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:29:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	13 Oct 2020 21:15:15

US3632032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User entered empty.	System	13 Oct 2020 21:15:15

US3632032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:13:08

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:34
User entered '19 Oct 2020'	Christina Bacher (b) (4) (b) (4)	22 Oct 2020 14:51:48

US3632032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:13:08

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:44:15
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Christina Bacher (b) (4)	22 Oct 2020 14:51:48

US3632032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:44:17
User entered 'Participant requested to withdraw due to health challenges and a new job, making it difficult to keep visits/study procedures.'	Christina Bacher (b) (4) (b) (4)	22 Oct 2020 14:51:48

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:52:32
User entered '19 Oct 2020'	Christina Bacher (b) (4) (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:44:11
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Christina Bacher (b) (4) (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:44:05
User entered 'Participant requested to withdraw due to health challenges and a new job, making it difficult to keep visits/study procedures.'	Christina Bacher (b) (4) (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:43:56
User entered empty.	Christina Bacher (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:43:58
User entered empty.	Christina Bacher (b) (4) (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:44:00
User entered empty.	Christina Bacher (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:08

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:44:02
User entered empty.	Christina Bacher (b) (4)	22 Oct 2020 14:52:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-MRNA-1273-P301000001'		

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
User entered 'No (N)'	System	30 Mar 2021 17:19:39
Un-reviewed for Safety.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
Signature has been broken.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Colleen'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Kelley'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '68 Armstrong Street' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered 'Atlanta' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'GA'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '30303' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:54:44
User entered 'US' (non-conformant).	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '5'	System	11 Nov 2020 16:31:54
User entered '4'	System	20 Oct 2020 11:55:35
User entered '3'	System	28 Sep 2020 12:20:22
User entered '2'	System	20 Sep 2020 22:10:00
User entered '1'	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-MRNA-1273-P301000001'		

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
User entered 'No (N)'	System	30 Mar 2021 17:19:39
Un-reviewed for Safety.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
Signature has been broken.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Colleen'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Kelley'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '68 Armstrong Street' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

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Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered 'Atlanta' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

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Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'GA'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '30303' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:54:44
User entered 'US' (non-conformant).	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '5'	System	11 Nov 2020 16:31:54
User entered '4'	System	20 Oct 2020 11:55:35
User entered '3'	System	28 Sep 2020 12:20:22
User entered '2'	System	20 Sep 2020 22:10:00
User entered '1'	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:13:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered '17/Sep/2020 11:07'	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:13:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-MRNA-1273-P301000001'		

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
User entered 'No (N)'	System	30 Mar 2021 17:19:39
Un-reviewed for Safety.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
Signature has been broken.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Colleen'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Kelley'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '68 Armstrong Street' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered 'Atlanta' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'GA'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '30303' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:54:44
User entered 'US' (non-conformant).	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '5'	System	11 Nov 2020 16:31:54
User entered '4'	System	20 Oct 2020 11:55:35
User entered '3'	System	28 Sep 2020 12:20:22
User entered '2'	System	20 Sep 2020 22:10:00
User entered '1'	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:13:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:46:16
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 19:41:35
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered '20/Sep/2020 18:09'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:13:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:46:18
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 19:41:42
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-MRNA-1273-P301000001'		

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
User entered 'No (N)'	System	30 Mar 2021 17:19:39
Un-reviewed for Safety.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
Signature has been broken.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Colleen'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Kelley'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '68 Armstrong Street' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered 'Atlanta' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'GA'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '30303' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:54:44
User entered 'US' (non-conformant).	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '5'	System	11 Nov 2020 16:31:54
User entered '4'	System	20 Oct 2020 11:55:35
User entered '3'	System	28 Sep 2020 12:20:22
User entered '2'	System	20 Sep 2020 22:10:00
User entered '1'	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:13:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:46:22
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 19:42:00
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered '28/Sep/2020 08:20'	System	28 Sep 2020 12:20:22

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:13:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:46:24
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 19:42:01
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 12:20:22

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-MRNA-1273-P301000001'		

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
User entered 'No (N)'	System	30 Mar 2021 17:19:39
Un-reviewed for Safety.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
Signature has been broken.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Colleen'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Kelley'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '68 Armstrong Street' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered 'Atlanta' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'GA'	System	20 Sep 2020 22:10:00

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '30303' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:54:44
User entered 'US' (non-conformant).	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '5'	System	11 Nov 2020 16:31:54
User entered '4'	System	20 Oct 2020 11:55:35
User entered '3'	System	28 Sep 2020 12:20:22
User entered '2'	System	20 Sep 2020 22:10:00
User entered '1'	System	17 Sep 2020 15:07:52

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:13:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:46:29
User entered '20/Oct/2020 11:55'	System	20 Oct 2020 11:55:35

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:13:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:46:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:31:41
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 11:55:35

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered	System	17 Sep 2020 15:07:17
'USA-US120-2020-MRNA-1273-P301000001'		

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

US3632032

Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'Yes (Y)'	System	17 Sep 2020 15:07:17

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
User entered 'No (N)'	System	30 Mar 2021 17:19:39
Un-reviewed for Safety.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
DataPoint Un-verified.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
Signature has been broken.	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 17:19:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:07:45
User entered 'No (N)'	System	17 Sep 2020 15:07:17

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Colleen'	System	20 Sep 2020 22:10:00

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'Kelley'	System	20 Sep 2020 22:10:00

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Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '68 Armstrong Street' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

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Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:08

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered 'Atlanta' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

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Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 11:55:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
User entered 'GA'	System	20 Sep 2020 22:10:00

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	02 Apr 2021 20:39:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 17:19:39
User entered empty.	System	30 Mar 2021 17:19:39
User signature succeeded.	System	30 Mar 2021 17:19:39
	Colleen Kelley (b) (4)	17 Mar 2021 19:00:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:13:58
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User entered '30303' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 16:01:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 11:55:24
User entered empty.	Christina Bacher (b) (4)	13 Oct 2020 13:50:14
	(b) (4)	

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:12:45
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:09:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:54:44
User entered 'US' (non-conformant).	System	17 Sep 2020 15:07:52

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
User entered '5'	System	11 Nov 2020 16:31:54
User entered '4'	System	20 Oct 2020 11:55:35
User entered '3'	System	28 Sep 2020 12:20:22
User entered '2'	System	20 Sep 2020 22:10:00
User entered '1'	System	17 Sep 2020 15:07:52

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Folder: SAE USA-US120-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:46:35
User entered '11/Nov/2020 11:31'	System	11 Nov 2020 16:31:54

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Form: Safety Report Form (5)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 20:30:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 13:36:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:46:37
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:31:54